UNITED STATES OF AMERICA

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ARMED FORCES EPIDEMIOLOGICAL BOARD

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BOARD MEETING

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TUESDAY

FEBRUARY 29, 2000

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The meeting convened at the Army Medical Center Department & School, Room 2407, Fort Sam Houston, San Antonio, Texas, at 7:30 a.m., Francois M. LaForce, Board President, presiding.

BOARD MEMBERS PRESENT:

FRANCOIS M. LAFORCE, M.D., President COL BENEDICT M. DINIEGA, USA, MC,

AFEB Executive Secretary

STEPHEN M. OSTROFF, M.D.
ELIZABETH BARRETT-CONNOR, M.D.
ROSEMARY SOKAS, M.D.
COL CRANDALL
DAVID ATKINS, M.D.
HENRY A. ANDERSON, M.D.
L. JULIAN HAYWOOD, M.D.
STANLEY I. MUSIC, M.D.
SUSAN P. BAKER, PhD

I-N-D-E-X

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Sero-Survey of Lyme Disease in the Military Cdr. McBride
Update: Anthrax Vaccine Immunization Program Ltc. Grabenstein
Back Injury Events Among Military & Civilian Air Force Personnel, (1988-1998) Maj. Carr
Executive session Board members

P-R-O-C-E-E-D-I-N-G-S

DR. LaFORCE: Call the meeting to order.

If we could, Col. Diniega has a couple of announcements to make before we begin the formal part of the program.

COL. DINIEGA: Just a few reminders:

The members, your travel settlements, and then when
you get paid, send a copy of the receipt.

On the agenda this morning, we have Cdr. McBride and the Lyme disease sero-survey talk, and he'll be followed, if we can unload the information on the laptop to the I-drive, Ltc. John Grabenstein will talk on the current issues with the Anthrax Vaccine Immunization Program.

And then if Maj. Carr finds her way here, we'll move the injury talks into this room, so everybody can have the benefit of hearing them. should be about а 15- or 10-minute Tt. Maj. Carr will talk on the back presentation. injury study she has in the Air Force, and Col. Valerie Rice will talk about the injury surveillance prevention program for the Fort Sam Houston garrison, and then we'll break into breaks.

Disease Control will remain here.

Health Promotion has only two members, so I don't know how you guys will want to handle that, if you guys will want to have your own meeting or split up and join other groups to help with the recommendations there. And you can have 3304 or use the corner or go down to The Pit, whatever you want to do.

And then Environmental Occupational Health will have 3305. And I invite the audience to attend whichever subcommittee sections that they would like to attend.

The breaks will be up to the subcommittee chairmen. If they want to work that through, charge through, or take a break. We all deserve breaks.

And then reconvene at 11:00 in a closed session, to include the preventive medicine officers and the liaison officers to the Board, and take a look at the draft recommendations, talk about the members that are rotating off and new members coming in, and also the next meeting. And then we should be able to close by 12:00.

I just want to take another show of hands for the tour, the AMEDD Museum tour at 1330.

(Show of hands.)

COL. DINIEGA: Six. Okay. We'll probably just watch the video and then have a self-tour over there. So have lunch and then we can meet outside here.

Taxis, if you're going to need taxis, let me know, but the number is seven 2s, and it's the Yellow Cab Company, and you can use this phone here. And they usually know where the helicopter is, so that's a good place to identify the pick-up.

Any questions?

(No response.)

DR. LaFORCE: Cdr. McBride, we're all yours.

CDR. McBRIDE: Very well. Good morning.

DR. LaFORCE: Good morning.

CDR. McBRIDE: I have a handout that I've given to the folks to reproduce. I'm told they've had some difficulty, and I'm told it'll be here in a few moments, but I'll go ahead and get started.

My presentation today is to give you a report on a recent sero-survey for Lyme disease, and before I get into my presentation, I want to just acknowledge the good assistance and remarkable

work that we've had with this effort from Capt.

Tamra Barker.

I was not thinking that she would be here, but I'm delighted that she's here, to stand up and receive some acknowledgment. But she's done a remarkable amount of work with this sero-survey and the data analysis that I'll be presenting, and I'm grateful to her. She's completing her preventive medicine residency at Walter Reed, at the WRAIR.

This issue first came to the attention of the AFEB in December of '98 when Col. Cody Sanchez presented some data of Lyme disease in the military. This was followed by a formal question to the Board regrading recommendation for the use of Lyme disease within the military population.

The AFEB's recommendation largely just concurred with what the ACIP had recommended, and they did not feel there was any need to really significantly stray from that. One of the -- thoughts were that we should perhaps, if we could, do a sero-survey of Lyme disease antibodies, Lyme antibodies, in our military population and see what that showed, and this is what we'll talk about.

First of all, I just wanted to review a

number of things. I'm going to just ever so briefly touch on the incidence of Lyme disease in the United States, and compare and contrast that to what we have found with our data systems for the Lyme disease impact in the military, and then give the results of the sero-survey, and then provide some conclusions.

This slide -- we're all familiar with this -- just demonstrates the areas of endemicity or high transmission of Lyme disease in the United States. You'll find it in your handout. And this represents the cases or the incidence of Lyme disease in the United States.

We can see that for several years, the incidence was increasing quite significantly perhaps, but in the last couple years, perhaps there's been some plateauing, and this past year, the cases were about 5-1/2 per 100,000.

Now, this slide represents the data that Col. Sanchez presented to the AFEB over a year and a half ago. I've added to the complete year of '98 and '99 the data that I received from the Defense Medical Surveillance System. These data were drawn from inpatient reporting and from the medical event reporting systems of the three

Services.

We can see that for several years, the cases were diminishing or presumably diminishing in the military, with the corresponding decrease in the cases per 100,000 person-years. This is not really a total 1.23, but just reflects an average of the cases over the past, I guess, nine or ten years.

And this, of course, dramatically demonstrates the incidence rates of reported Lyme disease, again through hospitalization data and through data received by the reportable events systems of the three services.

Well, I've added an additional slide to the material that Col. Sanchez presented to you, and I found it somewhat startling. And these are data that report the incidence of Lyme disease in the military, but you'll quickly see that over the past three years, these numbers are significantly higher than what were reported in the previous slides.

These data are obtained from what's called the SIDR and the SADR, both inpatient data record, as well as the ADS or the Ambulatory Data System. These are numbers that are generated

automatically largely from outpatient settings when patients are seen in a clinic. The provider checks a little box on a form, and this goes to the DMSS in a round-about way.

So some of this data, we don't really know exactly if it's meaningful or not. These represent people that could have been seen with a presumptive diagnosis of Lyme disease. It really wasn't, and it's very suspect. What I am told -- I'm told that these data do not -- are incident data, so that they do not reflect repeat visits to the clinic for the same diagnosis.

But these are kind of startling, because the rates are relatively high, and the cases show really very little diminishment over the past two or three years.

So I share this with you, just to be complete and to show you that we do have some problems and concerns, at least in my mind, with our reporting of Lyme disease, and perhaps this is reflective of other conditions in the military, through some of our systems that we're struggling with and trying to make sure that they're accurate and complete. So I just share this with you for what it's worth perhaps, and we may discuss this at

the conclusion of my presentation.

Anyway, just to summarize these points, overall initially we were seeing a decreasing incidence rate since 1990, notwithstanding the ambulatory data that I just showed you. And we know of a disease concentration. What I didn't show you was that there was male predominance in the military population, and that the incidence increases with age.

These were findings that were presented to you previously, that I've just summarized here from the previous presentation. And, of course, the concern about what appears to be an increase reported among health care workers, which we really can't deny. It's clearly shown in our populations.

And then lastly, with the initial discussion this morning about Lyme disease in the military, there was some recommendations that were opined at the earlier AFEB about how we could possibly use this in our military populations, and nothing really striking here, but just some obvious thoughts that were presented at that time.

Now, let's talk about the sero-survey.

We had about 10,000 specimens from the Armed

Forces Serum Repository that were made available to

us. These were specimens that were pulled out of the repository in Rockville for use in a hepatitis C virus sero-survey a little while ago, and so we still had some remaining serum for those, and it was an easy thing to do, so we just took of that 10,000 and they were able to test 9,673 specimens through the ELISA at USUHS. Cdr. Al Richards and his lab did that.

And then of those that were found to be positive by ELISA, a confirmatory Western Blot assay was performed. Now, the ELISA -- of the 9,673, approximately -- well, exactly 1,594 were found to be seropositive by ELISA.

Now, the next couple of slides I'll demonstrate, I just wanted to characterize that of these folks that were found to be ELISA positive, these reflected, I think, a wide range of representative of the people in the military, both by gender --

We can see that the mix of male and female was relatively -- the percentages were relatively the same between the total population of the 10,000 specimens that were accessed and then the ones that were found to be seropositive, and then similarly with age, we see the same trend,

with the majority of the positive cases being found in the 20 to 29 age group.

In contradistinction to what Col. Sanchez reported a year and a half ago, in the seropositive by ELISA, we didn't see a predominance in the higher range, but it was more reflective of the normal age range of our active-duty population.

And this is a figure that demonstrates the seropositivity by rank, and it's very similar. I'll just swiftly go through these, and then the last one is by Service. We do see, however, in this one, that where there are some significant differences in the Service mix population of the 10,000 specimens, we see there's somewhat of a flattening of that, and about 400 for each Service, except for the Air Force.

Oh, one more here on race and ethnicity. The vast majority, of course, are whites, and you can see the numbers there.

Do you all have your handout now, please?

VOICES: Yes.

CDR. McBRIDE: Thank you. And this last slide about the demographic characteristics of the sero-survey was just an attempt to show you

that there was a wide range of cases from across the United States. And I have -- and this just shows -- it's an attempt to demonstrate the distribution of the ELISA-positive cases by their home of record, the report of home of record.

Now, one thing -- I'll just pause for a moment and confess that one of the main things we were hoping to have when we did the sero-survey is to match those that were found to be sero-survey with what their geographic career history was. We have that data available at the DMSS, where we can track an active-duty member, as to when they came into the military and what duty stations they have had across the country.

But it so happens that when we obtained these serum specimens from the HCV work, they had sanitized those and removed all the personal identifiers, and that wasn't an important feature for them, and so they didn't ask DMSS to link those with the geographic history. And it wasn't until after we did the sero-survey that we said, Man, we don't have that important data. All we did have was a home of record.

So that's a deficiency, at least in my mind, that we weren't able to link that. But I

think you'll find that that is not significant, and here's why. We did the confirmatory seropositivity by Western Blot of the 1,594, and only 12 were found to be seropositive. And these were confirmed and double-checked, and of those that were found positive by ELISA, again 12 were found to be confirmed positive by Western Blot.

Now, on the last page of your handout, I have kind of a confusing chart, and it's shown here. You may not be able to see much of it on the screen, but please refer to it on your lap there, if you'd like.

Now, I've arrayed the 12 positive Western Blot specimens in this chart here. As you can see, five of them were from Army individuals, two from Navy, three from Marine Corps, and two from Air Force.

On the chart, we showed the date of accession. This is when the individual came into the military or came into the Service that is shown. The antecedent specimen date is the date that we have the matched serum that was drawn at an earlier time, and this is very insignificant, we think, because we were able to -- for nine of the 12, we were able to go back and find an earlier

serum specimen, run that, and see if it was positive or negative.

And then we have the gender, age, rank, race, home of record, occupation category for the individual, and their education level and marital status.

There's a couple of asterisks here.

The first two specimens, 1 and 2, they had an antecedent specimen, but it was negative, and so, of course, all of the serum that was tested with ELISA and Western Blot were drawn from a 1997 specimen. They were drawn in 1997, so these were two individuals that presumably sero-converted over the past years.

If you look closely at the first one, you see that, in his case, his antecedent serum specimen was drawn sometime after he was in the military. And then the one in 1997 was positive. The initial one was negative, suggesting that this individual sero-converted during his military service. So that's one seropositive -- sero-conversion that we have of the 12 that were found to be Western Blot positive.

The second specimen, number 2, this is a bit hard to understand perhaps, but their

antecedent specimen date precedes when he came into the military. A specimen was drawn, presumably in '91. Yet he was shown his accession into the Army in '95.

Well, the best explanation I've had from that from the DMSS was either this individual was in a delayed entry thing, where he had his blood drawn from an earlier physical, then waited around a while before he came in -- that seems an excessive period of time to me --

But the other explanation is perhaps he was in another Service and then crossed over to the Army, and we showed his accession date as '95 in the Army, but it was probably another Service.

We're going to look at that further and see if we can solve that.

So we don't know if he actually seroconverted while he was on active duty, because his
positive Western Blot, again, was drawn in '97.

His initial specimen was drawn in '91. Sometime
during those intervening six years, he seroconverted.

DR. OSTROFF: Can I ask -- I mean, it says he's only 22, so in 1991, he would have been how old?

CDR. McBRIDE: Fifteen or something.

He was really an early entry, so that's a significant concern. But it's only one, and we'll have to confirm those dates, but that's what we were given from the DMSS last week.

So the remainder of the antecedent serum specimens were positive, and then you see the last three that are shown, they happen to be both of the Air Force cases and one of the Marine Corps cases. There wasn't an earlier specimen available.

So all the other ones were positive, and some of them were positive early in their military career, some after some years, so we don't know for sure if they might have sero-converted before the antecedent specimen was drawn, but I guess we can only say that we had one clear conversion among these 12 that were found to be seropositive.

So these are the findings from the sero-survey. Let me conclude with this slide here. The concerns exist regarding the quality and completeness of the data, and t here's one that you brought to my attention that we'll have to clarify.

But then there is -- I think there is some uncertainty remaining about the true burden of

disease of Lyme disease in the military. There are data from inpatient and reportable events data that suggest that there's a diminishing trend, and then there's ADS data that suggests that it's still there and a concern. So this is something that we have to try to come to grips with and to clarify.

However, in this sero-survey, the very low number of sero-conversions, one, possibly two, suggests that Lyme disease is really not a concern in our population and that our people presumably are not significantly exposed to Lyme disease.

And, of course, this would benefit from additional studies, but these are the results from the survey that I wanted to share with you.

Just to close off, I want to just acknowledge the assistance of these good folk here:

Col. Sanchez, Cdr. Richards from USUHS, Capt.

Hyams who made the blood available to us and provided some assistance, and then the good people from the DMSS and the data they provided us.

That concludes my presentation. Are there any questions or comments? Dr. LaForce?

DR. LaFORCE: Well, congratulations.

This was -- I remember the meeting when this came up, and I particularly remember the cluster of Lyme

disease cases in Hawaii. And the experience that was described a year or two ago was exactly the same experience I'd seen as a clinician for 20 years.

The serologic testing was so flawed that you end up with a large group of individuals that you never quite know what it is --

CDR. McBRIDE: This is serologic testing that's flawed?

DR. LaFORCE: Oh, yes. Oh, the serologic testing is -- unless you have it linked with Western Blot, as you did -- this is why I'm so happy --

DR. OSTROFF: Or with clinical illness.

DR. LaFORCE: Right. Clinical illness, but the sort of stand-alone serology is, again, the issue that really causes enormous problems for clinicians in this area.

I think you now have very clear data that this is a nonissue or -- I mean, I would have to be convinced otherwise, and it, I think, would be consistent with pretty much everything else that we've sensed was probably going on with Lyme disease.

Steve, what did you think?

DR. OSTROFF: Well, yes. I mean, I can't emphasize it, you know, enough, what Mark just said, which is that just doing serology outside of the setting of the compatible clinical illness or with a confirmatory test just will mislead you in a relatively low-risk population.

And I'm actually somewhat surprised that there aren't more Western Blot positives, because they do engage in, you know, some relatively high-risk

I guess one of my questions would be in terms of the data that you presented from the outpatient setting. What information do you have about, for instance, where those diagnoses were made geographically, and what times of year they were made and things like that, because that would give you a very good idea of whether or not what you're looking at is real or whether it's not real.

I mean, those diagnoses should only be occurring in certain very specific geographic areas. They should be occurring during the high-risk summer time periods of the year. And so you could tell pretty easily whether that data is valid or if it's invalid.

CDR. McBRIDE: We can do that. We can

NEAL R. GROSS

activities.

go back and identify where these diagnoses were made or the discharge diagnoses were had. One concern, of course, with our transient population:

They may have been exposed someplace, to some -- and then perhaps transferred, and not brought to the attention of Medical at a different geographic location. But, nevertheless, we can do what you've expressed.

DR. LaFORCE: Yes.

COL. BRADSHAW: Just a caution. I was looking at your slides, and looking at the slides for home of record, it pretty much reflects the tax-exempt states.

CDR. McBRIDE: Thank you.

(General laughter.)

COL. WITHERS: It shouldn't, because they're not the same. I mean, our residences and our home of record are two independent -- well, not independent, but they're different.

COL. BRADSHAW: But if you look at 685 from Texas and 300-some-odd from Florida --

COL. WITHERS: Maybe you're looking at residences, not home of record.

DR. LaFORCE: Other questions? Yes.

COL. SMITH: I have a concern, Wayne,

about misdiagnosis of Lyme's because I think quite often it's not diagnosed. And I'm wondering if you have any hint of -- could you have used the serum repository, something of that nature, to pick up a number of people that, in fact, were Western Blot positive but were never diagnosed with Lyme's disease, because I do wonder if you've got a significant number of people who simply haven't been diagnosed. It's very difficult to diagnose it. I know; I've missed it myself a couple of times and then had to diagnose in retrospect.

CDR. McBRIDE: I don't have an easy answer for that, but what I did do last week was asked the DMSS, even though there were no personal identifiers on these cases, did it have birth dates; did it have some demographic data.

They went back and looked at all the cases that were reported in the military, and they matched them with birthdays and the other demographic features that we have on these 12 cases, and they found that there were none that matched; there were no cases that we've had that correspond to the 12 Western Blot positives that we found.

COL. DeFRAITES: This is Col.

DeFraites. Just to clarify, this population that we used for the sero-survey was a stratified, random sample of persons on active duty in 1997, without regard to their location. Starting with that population, the ELISA was done as the screening test.

So are you thinking that there are people who are Western Blot positive who are ELISA negative?

COL. SMITH: Well, the serology, like you say, is so confusing that sometimes your ELISAs just totally confuse you. I'm wondering if you just did Western Blots that --

COL. DeFRAITES: Well, I don't know. I guess you'd have to look at the dynamics of the antibody to see. I don't think so, though. I think the ELISA -- if you're negative ELISA negative, you can be Western Blot negative.

DR. OSTROFF: But there is one point worth mentioning, in that some of these people could conceivably have been exposed in Europe, where, of course, the Lyme disease and the organisms themselves are not the same ones that we have in the United States. And I'm not quite sure how good our ELISA and Western Blot perform for the

European variance of Lyme disease. So that's one potential thing to think about.

DR. LaFORCE: Well, I would say the European --

COL. DeFRAITES: The vaccine is only effective against the strains in the United States, so for purposes of looking at vaccine policy, this is still probably --

DR. OSTROFF: Well, that's right. But, I mean, if you're interested in knowing whether or not some of these ELISAs may actually be positives, you would have to go and follow up through the Western Blots.

LTC. KRAUSS: Col. Krauss. I just wanted to comment on the ADS data, because as I reported yesterday, in the tuberculosis field, it just didn't relate to reality. When I was at Madigan, I used to routinely follow up all the serology for positive Lyme titers, usually the ELISA.

And what I found was neurologists routinely did Lyme serology on anyone who had any neurological disease, and the way that the ADS works -- I'm not sure if the Board has seen the ADS, but the clinician just checks off what they're

doing. And if they're doing a rule-out Lyme, they would check, Lyme, and it would go into ADS as Lyme disease. There is no rule-out diagnosis on ADS.

So a neurologist at Madigan would be checking, Rule out Lyme, on all their neurological disorders. Even though they don't think it's Lyme, they'll check it.

DR. LaFORCE: Right.

CDR. McBRIDE: That's a very good point. Thanks a lot.

DR. LaFORCE: But, again, the power of a randomized, stratified sampling is to answer the question: Is this a problem in the military? And the answer clearly is no.

CDR. McBRIDE: We have one more comment.

LTC. FONSECA: Just for Dr. Ostroff and the others who are wondering why it wasn't higher than they expected, even though we go crawling around in the woods, and even though the personal protective measures that soldiers, sailors, airmen, and marines take may not be as high we would like, they're still far higher than what civilians do, crawling through the woods, like the pyrethrintreated uniforms, for example.

So there's other personal protective measures that would mitigate the tick-borne disease risk.

COL. DeFRAITES: There's also another issue, I think, with Lyme, and that is the practice that I saw. It's anecdotal, but there's the practice, for example, at Fort Dix, New Jersey, where persons who come in with a tick attachment are treated with antibiotics. And I think if that practice is widespread, this may blunt some of the antibody response, if that's widespread. I mean, that's just a possibility.

The other thing about ADS is that, again, I agree with Dr. Krauss. You don't know what that visit was for. If they came in with a tick attachment, that could also be a rule-out Lyme or possible Lyme condition, so it could be a number of things.

And I think looking at the geographic distribution will help sort that out a little bit, but I would suspect the same thing, that that's why you have patients in Hawaii being evaluated for Lyme disease, is some are the chronic manifestations --

DR. LaFORCE: Thank you.

COL. DeFRAITES: Can I ask one -- what's the rationale behind treating anybody with a tick attachment with antibiotics?

DR. LaFORCE: No, no. Don't ask.

COL. DeFRAITES: The rationale? I think the rationale is you do what you can for the patient that's in front of you. A lot of these guys at Fort Dix are reservists that are going home, and so the doctor feels like they got to do something. Besides, it's the Air Force doing it, so I don't know why.

(General laughter.)

COL. DeFRAITES: The Air Force is responsible for medical care at Fort Dix.

COL. DINIEGA: We added three speakers at the last minute, and Col. Grabenstein is one of them; Maj. Carr; and, I think, Col. Rice who's not here yet. And I just want to thank them, because it was very last-minute. I think I talked to John on Thursday or something, you know.

LTC. GRABENSTEIN: Forty-eight hours is advance planning for us, so that's not --

COL. DINIEGA: So I want to thank the last-minute speakers for making time on their schedules and rushing to get here.

And then one other reminder for everybody, the Board and audience. If you can remember to sign in, because we need a sign-in for both days. You don't have to repeat everything on there. Don't put your e-mail again if you signed it in once and your phone number, et cetera.

DR. LaFORCE: Col. Grabenstein.

LTC. GRABENSTEIN: Thank you. My name is John Grabenstein. I'm the deputy director for the Anthrax Vaccine Immunization Program Agency, a cell within the Office of the Army Surgeon General. Col. Diniega and Dr. LaForce asked for an update on the controversy or the uproar regarding anthrax vaccine, which those of you who have been reading the newspapers have a piece of.

I am in briefing fatigue and have forgotten to bring out a handout. I'll leave the hard copies with Col. Diniega and can provide email copies to anybody who's interested.

The controversy, where does it all start? I think the start comes from the assertions of the unexplained illnesses among Gulf War veterans, but took on life of its own, thanks to the technology of the Internet, with anthrax-NO listservs and anthrax-NO web sites of various

sites.

There have been now seven congressional hearings, primarily focused with a very skeptical audience, if I may say, in the Committee on Government Reform in the House of Representatives, and a relatively good reception in the House Armed Services Committee.

What you have seen in the newspaper most recently: The <u>Atlanta Journal</u> had the headline, "House Panel Rips Anthrax Vaccine," about a week, and it was the draft version of what was written by the majority staff, not yet adopted by the committee or the subcommittee from Congressman Shays' subcommittee on international relations of the Committee on Government Reform, about a week ago, ten days ago.

There also have been six GAO studies of varying degrees of inquiry. I would submit to you that some reporters have done an excellent job of trying to riddle out the facts and figure out the allegations from the facts, but not all reporters have done that.

And one thing that, if I can categorize it, I would call it dueling quotations. Somebody would say, The moon is made out of green cheese,

and then, But the Department of Defense denies this, and without getting far into the facts of what is known, how should quotes be understood, what's the theoretical -- you know, whether this is just abstract speculation, or whether there's scientific basis to the assertions.

And one of the problems with the public, I think, is that not many people understand in an objective way the difference between a coincidence and a cause-and-effect relationship. Epidemiologists deal with this all the time, but it is not common public understanding.

There have been various subtangents to all of this assertion, that the vaccine was intentionally or unintentionally spiked with mycoplasma, a finding disproven at USAMRIID in a variety of ways; the assertion in the medical journal of <u>Vanity Fair</u> in 1999, that the Government had intentionally put squalene into the vaccine.

That assertion has now morphed into an article in the February 2000 issue of Experimental Molecular Pathology, in which the same authors, now in a reportedly peer-reviewed journal, that does not make that reaching assumption, but simply says that, Golly, there are anti-squalene antibodies in

Gulf War veterans.

Col. Carl Alving and I have proposed a letter to the editor, to Experimental Molecular
Pathology, which I have a verbal understanding is accepted, that refutes the tenuous scientific basis of that finding. And this is a mere summary.

Now, who questions anthrax vaccine? I have crafted this slide, intending to give due credit to honorable people. I do not mean to criticize people at all, as you'll see from the variety of categories.

We are increasingly aware there is a subset, a pretty small subset, I think, of the population that think that vaccines are unnatural; people who are very hyper-concerned about side effects; who dislike things mandatory; who pay attention to 60 Minutes and similar programs intensely and respond to alarms, is how I categorize that; distrust the impersonal government.

I was at Pope Air Force Base yesterday, giving a briefing to the medical staff and the wing and squadron commanders there, and one of the preventive medicine physicians made the comment that what we may be seeing is a lot of referred

anger, people angry at the Government for one reason or another, taking it out on the vaccine.

And I think that's not an unreasonable assertion.

Fear of needles; never thought about vaccines much before, and all of a sudden this is in the news, and they don't have a factual basis upon which to judge vaccines, so they are, to some extent, at the whim of the winds.

There is a very small subset that thinks that it distracts from nuclear disarmament issues. Some of the issues, I think, with pilots relates to disruption of primary income; doubt or denial of biological warfare or biological terrorism as a threat; and certainly a variety of others. This is merely a beginning to try to categorize these folks, and to make the point that it is not a monolithic group at all, and many of these subgroups have very honorable intent.

I think Mort Walker understood this extremely well when Doc asked Sgt. Snorkle which arm he wanted the vaccination in, and he grabbed Beetle Bailey's.

So how do we handle this? We keep ourselves rooted in the facts, because if we stay with the facts, we can't go too far wrong. And

this is the summary of the efficacy data for this vaccine.

Human studies, primarily the Brachman study, as many of you are very well aware, where the vaccine worked against both inhalational and cutaneous anthrax, statistical tests providing limitations certainly, but the CDC observational study that followed on showed disease in the unvaccinated group and no disease in the vaccinated group if you got at least three doses.

And then the animal challenge studies, which, for the other biological warfare threats. is going to be the only kind of efficacy data that we have, after all, or the primary, I would say.

But in Rhesus monkeys with masks on their face, delivering hundreds of time the lethal dose of anthrax spores, 95 percent protection; in rabbits, 97 percent protection; in guinea pigs, 22 percent protection, but the pathology and the immunology would suggest that the first two animal species may be more relevant to humans than guinea pigs.

Nothing makes me angrier than the press reports or the assertions on a certain hill in Washington, D.C., that there are no safety studies

of this vaccine. There are, in fact, 12. And the sample sizes for these studies ranged from the dozens to the thousands, and not all of which are published.

And one of my goals for the year 2000 is to get as many of them published as we can. I can provide you detail on any of these, and I think I have in various forms in the past.

Next on my list of irking remarks is that there have been no -- that we really ought to have independent scientific review of this vaccine, and in fact, a retired three-star general had that in the op ed piece, front section of the Washington Post, Sunday edition, op ed section a few weeks ago. Thank you very much, General; we've been doing that for quite some time.

The FDA panel was convened in the late '70s, reported in the <u>Federal Register</u> in 1985; yourselves have been watching this for quite a few years.

The Advisory Committee on Immunization Practices has reviewed the vaccine in general and has a working group on bio-defense, which is at a very advanced draft stage of having an ACIP statement on anthrax vaccine, odds are, you know,

God willing and the river don't rise, to be approved in June or so, to appear in NMWR in August or so. Obviously that's contingent on approval of the document, but that's the way things are looking.

We refer every VAERS form on anthrax vaccine to a separate committee, chosen by the Department of Health and Human Services, called the Anthrax Vaccine Expert Committee. They are -- we met last week in Rockville at the HHS building to work on their first-year report, and they were doing their strategic planning on which analyses, which stratifications to report out on that, and the intent is to produce a manuscript to be submitted to JAMA.

At Johns Hopkins University, there's a set of folk with some liaisons, I think, from this room, the Working Group on Civilian Biodefense, published -- that's the Englesbee [phonetic] article from JAMA of several months ago, last spring, I guess, and Dr. Burroughs' review, a member of the National Academy of Sciences.

We are contracting -- we are in the contract negotiation stage with National Research Council, NRC, to do a soup-to-nuts, absolutely

every fact ever gathered, open public session, review of the vaccine. The assumptions are that we will -- an OIM-style expert committee.

The assumptions are that it will begin its proceedings in the late spring and may take two years to produce its final results, with all the quality controls that they have to their products.

There's some e-mail traffic that I don't know fully, but there's a possibility of a letter of findings from a previously established IOM committee on what their opinion of anthrax vaccine in relation to Gulf War illnesses is to date. I don't know that as a solid -- more solidly than I've described it.

What else are we doing? We have a finite amount of vaccine, and we are awaiting the licensing of the new facility in Lansing with the Joint Program Office for Biodefense, collaborating very intently with BioPort to get that licensing accomplished as soon as possible.

Our safety -- I showed you 12 safety studies. We are not done collecting safety information on anthrax vaccine. We never will be, as we are not with any vaccine or any drug, and certainly a wide variety of efforts underway as

well, key among them being additional long-term safety studies, and I emphasize the word "additional," in addition to the ones we already have from the Special Immunization Program at USAMRIID.

I have a couple of slides I'll show you here of some temporal medical database studies. We are doing relative risks -- me, I'm not. The good folks at Army Medical Surveillance Activity, Defense Medical Surveillance System, as well as the Naval Health Research Center at San Diego are working on database studies to compare vaccines to non-vaccines and even vaccines before and vaccines after vaccination. And we've got one set of reports that are in their quality control edits now, with additional studies to follow.

As you may know better than I, there is a proposal for DoD/Veterans Affairs millennium cohort study or very large longitudinal study. We will be able to ask anthrax questions of it, and one of our foci is reproductive health in all of these efforts.

Education tools: Web site keeps getting expanded and expanded. We are on the road constantly. Somebody is giving briefings or

information updates to a variety of constituencies; working with the CDC on perhaps hosting a meeting in the spring with the Military Coalition, the Retired Officers Association, and the NCO Association, and the various proponency groups for service members, retired and active and reserve, for that matter.

We have a video that has just finally gotten its final approvals. We're working on the distribution plan now, as an educational effort, a CD-ROM a little bit further back. Our 877 number gets about 80 calls a month. Our e-mail question-and-answer service gets about 160 inquiries a month on average.

One of the leading proposals out of some money provided to the CDC for anthrax safety research is a proposal that Col. Engler, Renate Engler, is essentially the lead for, and that is to put some teams of nurse practitioners and support personnel in some settings, the number to be decided by the budget, to assist in working up adverse event cases; for example, Guillain-Barre cases or optic neuritis cases or cases of interest, so that we get full information on them in more detail that we might otherwise, and also providing

outreach education on a more regional basis.

We have pilot data that would suggest that giving -- removing the two-week dose and changing the route to intramuscular is just as good immunogenically and safer in terms of injection-site reactions. CDC is about to issue the request for contracts for the larger, 1,500-, 2,000-person study that would be the definitive measure in that regard.

NRC review, I've mentioned the AVEC report pending, the ACIP recommendations pending. There will be more animal challenge studies.

There is a recombinant protective antigen vaccine that is much further behind or much further back in the pipeline. USAMRIID and NIAID are collaborating on that effort, but it will be quite a few years before that progresses.

This is temporal trend data; this is ecologic data, subject to all the limitations thereunto attached, but to worry -- this is Defense Medical Surveillance System. We've had assertions that the anthrax vaccine is killing people, so we looked at crude death rates, actually death due to illness.

These are rates, annual rates per

100,000 active-duty personnel, and so your odds of dying of illness while on active duty had been about 1 in 10,000. I do not assert that it is falling. I simply assert that it is not rising.

And then down here you see hospitalization rates for Guillain-Barre, for erythema multiforme and for aortic various stories behind why each one of those is on this list. But, again, I do not assert that these rates are falling. I assert that these rates are not climbing.

So where do we go from here? Col. Diniega asked me to speculate on how the Board might help or at least begin the consideration for your discussion. And we certainly have a very active effort on Capitol Hill to try to explain the value of this vaccine to people. You have gone on record in the past regarding your perceptions of the value of the vaccine.

Perhaps an update along those lines would be appropriate. Perhaps an article or an editorial for one of the mainstream journals would be appropriate, from your perspective in analyzing the value of the vaccine.

And on the plane flight down here, I

finally got a chance to carve out time to read your big red book, and we are grappling with how to implement all the good ideas in there and make them happen and find the money and figure out the structures for getting the education accomplished and getting the resources for the personnel, not just to vaccinate the troops but to vaccinate them well and with high quality and with education and information. And we certainly do not have the magic answer for that yet, but it is very important to us.

One of the things Col. Engler and I were speculating about down in Atlanta a few days ago was whether or not we should have a list of who the vaccine-givers are and that they have to have gone through at least a certain number of hours of videotape watching or some minimum standard.

We are still at the very early stages of figuring out where to proceed, and I'm sure others have thought more about this than I. And in your big red book is mentioned at several points some sort of steering group or working group or advisory group or what have you, that would focus on not vaccine policy but vaccine implementation, and what shape that takes is a subject of interest

to us. I do not claim to have the answers at all.

I'll pause there and see if I generated any questions.

DR. LaFORCE: Questions? Col. Diniega.

COL. DINIEGA: Isn't there a danger, a considerable danger, when you treat this licensed vaccine unlike other licensed vaccine, and you just draw more attention and raise suspicion that there might be something wrong with this vaccine?

LTC. GRABENSTEIN: Much ado about nothing. Yes. But the dilemma, I think, is with all the disinformation circulating, you have to have a pro-information initiative.

COL. DINIEGA: That's true, but I take issue -- the issue I have is this credentialing business for vaccine providers.

The other comments: I think the Board is willing to help, and we can discuss that later on in the subcommittee, as to how they can help.

DR. LaFORCE: When I spoke with Phil Brachman -- this would have been maybe about a month ago, when I saw him -- he wanted -- I was sort of bringing him up to date in terms of all of the information that we had received on AFEB. And he made a specific request as to why this summary

hadn't been sent to the MMWR, to use the MMWR really as a vehicle, to actually get some of the information that you've so carefully pulled together.

And he -- and I'm sort of asking the question through Phil, who said, Gee, if you could just put that on the table, he said, that might be a way of helping things along.

LTC. GRABENSTEIN: And other than a quick summation for the MMWR -- I mean, the ACIP is pursuing the proper long-range goal of the -- essentially the review article and the policy article, which is just the wheels of the machine take more months than we'd prefer sometimes.

There was a good review article by Dr. Friedlander, Col. Friedlander in JAMA, December 8 or so, which reviewed some of the efficacy data as well.

DR. OSTROFF: I seem to remember about six months ago, we actually had some e-mail traffic back and forth, about putting something in the MMWR that was going to review sort of some of the safety data, and it just disappeared.

CAPT. TRUMP: No, it hasn't.

LTC. GRABENSTEIN: Yes. Some of the --

the Tripler study, the Korea study will appear -I guess it's in press; I think it's been accepted
now. It's almost been accepted.

CAPT. TRUMP: I think it's been accepted. Yes.

DR. LaFORCE: Accepted where?

CAPT. TRUMP: MMWR, in collaboration with --

LTC. GRABENSTEIN: But it's safety only, not efficacy.

CAPT. TRUMP: And then the separate issue is the ACIP recommendation, which is a very extensive review of safety and some of the issues like, you know, promising information about alternate routes, shorter number -- smaller number of doses.

DR. LaFORCE: Right. And that will appear as the separate little monograph that's part of that series. Right?

LTC. GRABENSTEIN: The indication is it would be a supplement, and, in fact, the fellow who's in charge of turning those supplements into CME articles says he wants to turn it into a CME article, which is --

DR. LaFORCE: Okay. Stan?

DR. MUSIC: Do you have any kind of summary of adverse event data that you could quickly show us, so that we could see what this vaccine does in --

LTC. GRABENSTEIN: On my laptop I do, and we had trouble getting the wires connected. Do you want a verbal or -- I mean, how many minutes?

One minute or --

DR. MUSIC: The chair has to --

DR. LaFORCE: No more than five.

COL. DINIEGA: Col. Bradshaw had showed some data, and thought that you would go into it a little more.

LTC. GRABENSTEIN: Yes. I mean, this vaccine causes injection site reactions. Let me talk -- I'll separate common events and rare events.

Common events: Vaccines hurt. This vaccine causes subcutaneous nodules. Thirty percent of men, 60 percent of women have an injection site reaction. See, I really do have this memorized.

This is injection site reactions, and the following one will be systemic events.

There seems to be a bias. If you

collect data in an occupational health mode, you get low numbers. If you hand out surveys to people, as we do in the modern era, you get higher numbers.

And shots hurt. Between 30 and 90 percent of people report a subcutaneous nodule. The injection site reactions less than an inch are about 30 percent in men, roughly 60 percent in women. Larger become rarer, and depending upon which study, it's either less than 2 or less than 1 percent have a really big reaction.

DR. MUSIC: Is this supposed to be IM or subcu-?

LTC. GRABENSTEIN: This is administered subcu-. If you administer it IM, these rates fall to single digits, 5 and 9 percent-ish, and in 173 people, I don't think they had one this big.

And here are systemic events. Let's use the survey style, which is more akin to what we do nowadays. There's a background risk of headache, some amount of fever, but the largest number here is muscle ache. These are all transient events, disappear -- self-resolve within essentially 48 hours, plus or minus. So these are the common, expected side effects.

We think if we can change to IM, we get rid of a lot of this. It's just -- that study has to go out in real time to support modification to the package insert.

I am drafting a policy for Dr. Bailey to consider, which would essentially create a corporate standard for individualizing care to somebody who has had a bad injection site reaction in the past, enabling them to go to IM in that individual, recognizing that as a corporation, we can't choose to consciously deviate from the package insert en masse.

DR. LaFORCE: Ben? Steve?

DR. OSTROFF: One question I have: I mean, you know, to some degree, in looking at this, it's like you're a salmon swimming upstream, against the tide of people who are so unhappy about this particular problem. You had this whole list of potential reasons why people are so unhappy.

What sort of behavioral research is going on, to try to address this issue, because this is not going to be just an issue for anthrax vaccine; it's going to be an issue that you're going to have to confront every time you try to put in some sort of a new intervention.

LTC. GRABENSTEIN: There is one effort underway with George Washington or Georgetown -- I forget which -- taking advantage of a VA contract vehicle, to look at risk communications, but I'm not satisfied that that answers -- that study is going to answer your question, and I think we need one. But I don't know how to -- who to approach or how to describe that.

COL. Defraites: This is Col. Defraites. It's very interesting in the meantime since the Gulf War. We instituted the policy of universal hepatitis A immunization and the vaccine that is really licensed, and we basically were able to implement that across the board with hardly a whimper.

I think there's a lot to be said about what is the dynamic of this particular intervention. I don't think we got that problem with every intervention. That's the point I wanted to make. But I think there's some special things about anthrax vaccine that make it special.

I think there's a high hope -- there's a lot that we can learn about this, and I just hope that we're able to capture a lot of this.

COL. BRADSHAW: This is Col. Bradshaw.

I think speaking to that issue, if you look at hepatitis A, it's a two-shot regimen, and the side effect profile for that vaccine is among the lowest of any vaccine. And I think the fact that it's a six-shot regimen over 18 months and it uses an alum adjutant and it's a fairly reactogenic vaccine are two of the issues that make -- and the other issue is the fact that the perceived threat is still not believed by a lot of people, and --

COL. DeFRAITES: Well, there's another trade-off with hepatitis is that you said, now you no longer need to get the gamma globulin shot; you can get the hepatitis A vaccine instead. And I think if there was anybody who doubted, I think that won them over, if there was anybody who questioned --

DR. LaFORCE: Finish --

I think that there's a lot of opportunity with the six-shot regimen for people to associate a clinical event with a shot. There's about -- a normal average person, male, has a little over two visits a year; female, a little over three visits. And so you get six shots over 18 months; you have a lot of opportunities to coincidentally associate an

untoward event with the vaccine.

And then just the fact -- just to get reminded every few months or weeks that this thing does hurt when you get it, and then when you perceive that there's not a big threat, and then you have the other issues of Internet, the power of the Internet, the geometric spreading of rumors, those are issues.

DR. LaFORCE: Yes.

LTC. FONSECA: I'd like to comment on what Dr. Ostroff brought up, because that's exactly what I was going to say. Right now, all of those on the list of Why would you distrust it, all the things that you've mentioned so far are good, but they wouldn't change the mind of virtually anybody on that list.

So even if you push MMWR, you're going to convince medical people, and that's good. But the real problem that we found out is all the veterans of the Storm, after the Storm, which there are several in this room that dealt with the Gulf War right when it was fresh.

And what we learned at that time -- and it's in Joshua Lederberg's report, the very first IOM report, that a large portion of this problem,

these things that happened after wars, was related to trust versus mistrust, and that the underlying theme -- and it doesn't matter whether it's anthrax now or PB or whatever it is the next time -- until we grapple with the issue, How do you get most of the Service members to trust the Services and the Government, that we care about them as individuals, this is going to happen over and over again.

So what I would suggest to the Board is that you reach out in more of -- the military social workers have done a lot in this area. There are sociologists at WRAIR who've looked into this. The psychiatry department at USUHS has looked into this, and to deal with our problems.

I think one of the strongest recommendations that you could give is something that's not medical at all, and that is getting:

What steps can the military take -- and I think we're on the right track right now, with improving housing, improving health care.

One of the comments that is in the medical world: When we first started the CCEP and we brought in all of the CCEP providers and we talked to them, what they almost uniformly told us,

why people were raising their hand, active-duty members, was that they thought they could get better care going through the CCEP and see what kind of providers they wanted to see, that their access to the kinds and ways of providers they want was improved if they raised their hand and they said they were a Gulf War person, rather than just the average Joe with a back pain or knee pain or rash or whatever.

So there's a lot of things on there that are going on right now, so the political environment is such that they want to improve the quality of life of service members, and I think that would go a long way of gaining one's background, but making recommendation to the DoD that could have much more widespread beneficial impact than purely staying in the medical world.

DR. LaFORCE: Yes, Rosemary.

DR. SOKAS: I have a question. I know Col. Warde presented in the past that in Great Britain, I think, the use is now voluntary or people get to choose. And I'm just curious, maybe not today, but, you know, what the acceptance rate has been. Has there been different health communication? How has that worked out?

COL. WARDE: The program was always voluntary. It's discontinued, because vaccine is not available at the moment. And it was only offered for troops going to high-risk areas. And the acceptance rate was 30 percent.

VOICE: But all your immunizations are voluntary.

COL. WARDE: That is true.

DR. LaFORCE: Col. Bradshaw?

COL. BRADSHAW: Actually, I was just going to follow up on that, but he said what I wanted to point out, which is the acceptance rate of anywhere from 30 to 80 percent maybe is one of the better numbers that I've heard in some units, but it's unit-specific in times, and 30 percent, I think, is the number that you had given us before as more the broad perspective.

And for a threat that is 99 percent lethal, to expect that perhaps two-thirds of your force would be lost in a mission, in effect, I think is unacceptable for us. And it's not that we don't have other vaccines that are mandatory. We have vaccines that are mandatory for going to school, for going to college, you know, for doing -- you know, occupational. So it's not that

this is that different.

DR. LaFORCE: Okay. Yes.

COL. BRADSHAW: Just back to the topic of expert articles, John, just help me, because Friday I saw e-mail traffic about an article that's coming out, apparently a strong article in the Journal of Aerospace Medicine, but it didn't say who wrote it.

LTC. GRABENSTEIN: It's the Health Affairs team, with --

CAPT. TRUMP: Mazooke, Claypole, Trump,
Bailey --

COL. WITHERS: That's coming out in March Aviation, Space Environmental Medicine. Of course --

DR. LaFORCE: On the anthrax vaccine?

CAPT. TRUMP: Well, it's on force health protection, with the anthrax vaccine as the example of why decisions are made, and based on science, hopefully, and not on political pressures.

DR. LaFORCE: Yes.

PROF. BAKER: I just wondered whether you're anticipating that the proposed NRC review will generate statements that this is so controversial that it's requiring an NRC review,

and we're not going to know for two years whether the NRC endorses the vaccine.

LTC. GRABENSTEIN: I don't see the fact that we've gone into the NRC process as a negative at all. The only negative is that they can't finish it by this weekend, that it's going to take a while to get there.

But from what I'm told, the NRC and the OIM is held in very high esteem on Capitol Hill, and they believe that their process is so rigorous that they come up with the right answers, and it's well worth investing time and money to get it accomplished. This is all --

DR. LaFORCE: We should wrap this up.

Any other comments or issues?

LTC. SMITH: Just one.

DR. LaFORCE: Yes.

LTC. SMITH: John, on those vaccine health centers, those are going to be focusing on all vaccine adverse events or anthrax?

LTC. GRABENSTEIN: Well, primarily anthrax, but, you know --

LTC. SMITH: I would suggest that would be a mistake.

COL. DeFRAITES: Yes. I agree.

LTC. GRABENSTEIN: Which way?

and basically made sure that all the anthrax reactions were worked up fully and ignored any other ones, all of a sudden, anthrax would have the highest number of -- obviously, that's a problem.

CDR. MURPHY: John, just to kind of follow up on that -- Cdr. Murphy -- I commend a lot of work that the AVIP has done, you know, and I think that it would be worthwhile, since we've expended this time and money and your personnel and staff and everything, to even expand it, you know, to make it, you know, risk communications for all vaccines, so forth and so on, because, again, this is -- as Col. DeFraites and Col. Diniega said, it seems as though we're pushing this one up into the stratosphere for everyone to look at, where a lot of the same things are happening with all the vaccines.

LTC. GRABENSTEIN: We do try to make sure that our policies are cogent for all vaccines. The clinical practice guidelines on adverse events say, Adverse events after anthrax and other vaccines, and there's a variety of other examples. We're cognizant of that, and as soon as we get the

ripples died down, we'll be happy to do more on other things.

DR. LaFORCE: The only -- I would close by saying that as president of AFEB, I really have got real concerns about -- as I'm sure everybody here has, about the hysteria and the absolute idiocy about some of the things that get just simply accepted as fact, when you read editorials in reputable newspapers.

I mean, I'm not talking about some scurrilous rag. You're talking about a <u>Washington Post;</u> you know, editorials in the <u>New York Times</u>, in <u>Atlanta Journal and Constitution</u>. And these, I think, are symptomatic of everything that we've been talking about; you know, this sort of distrust, this sort of miasma that exists when you talk about anthrax.

All of a sudden everybody sort of starts feeling funny about it. And I must admit: I think any efforts at all in terms of continuing to reiterate that care is being taken, inordinate care, in terms of this particular program -- I think every single iteration adds something. And I just would like to make sure that whatever use the sort of bully pulpit within the AFEB can be of

value to the Services, that that be used.

LTC. GRABENSTEIN: If I could, I think the two most tangible products would be the first two I listed on the slide.

DR. LaFORCE: Yes.

LTC. GRABENSTEIN: The letter and perhaps some medical publication. And we'll be happy to work with you.

DR. LaFORCE: Super. Okay. Thank you very much.

We should break up into the subcommittees --

COL. DINIEGA: No. One minute. Injury.

DR. LaFORCE: Oh, yes. I'm sorry. The back injury presentation. It wasn't on my initial calendar.

MAJ. CARR: I'm Bridget Carr from the Air Force Safety Center. I'm an epidemiologist, and as Col. Diniega said, I was expecting to just, around the table, chat with the subcommittee members for the injury group, so what he just distributed were my notes, actually, for talking about this around the tape.

We conducted a large back injury study

from reports that were sent to the Air Force Safety
Center on back injuries from civilian and military
workers, and some of the notes are just highlighted
in paragraphs that are numbered.

Our purpose for bringing this to the AFEB was just because back injury is so common, costly, and debilitating. There's a big DoD burden in claims, and it remains a prevention challenge, as those of you who read the literature can attest to. We are posting a big technical report on this study.

The study's mostly descriptive, and we're looking for the usual suspects, such as age, sex, tasks, and activities that were associated with the incidents of reporting back injury.

But by reviewing these cases as they come into the Safety Center, we had a couple of hunches that there was an association between number of lost workdays and whether or not the person was a civilian worker or a military worker.

And also it looked like there was the potential for an association between the day of week and whether the injury was reported to be associated on or off duty, so we pursued those two things.

The methods, I can skip over that. We

deliberately extended motor vehicle mishaps, because that's -- for one, that's another study. We were trying to look more for just people who were doing things and specifically over-using their back, and not just that happened in another mishap, for example, in a car crash.

Our data sources were the injury events reported to the Air Force Safety Center. We looked a little big in some FECA claims, and then we had the personnel for our population demographics from military and civilian workers.

So you see we presented some risk estimates for differences between military and civilian and age effects and sex effects, but just drilling right down to the three of interest, there was three issues that we wanted to -- that we will be emphasizing in this publication.

One is that for the military, in case you don't know, a reportable event, definition for the Air Force Safety Center is that an active-duty member who loses a day of work, subsequent to their injury, become a reportable event. And these are for events that happened on or off duty.

For the civilian workforce, it's just duty-associated injury events. So for the military

population, in this sense, then, we watch them 24 hours a day, if you will. There's definitely a strong off-duty association with reported back pain events, and I have the risk estimates there for you.

And on the good side, in the last three years, that proportion has decreased a little bit to -- what was it? -- just 28 percent over the last three years, compared to almost twofold when looking at all eleven years rolled up.

The second area of emphasis was this difference in days of work lost. The crude estimate is civilians lost over fourfold, almost fivefold more time, and because, as you might imagine, these data are very right-skewed, it was from one to, in some cases, 180 days, we just analyzed the median, and I presented sex-specific and age-specific risk estimates there on the median analysis.

If you looked at the quartiles over these statistics over the eleven-year period, all of them declined. The gap, however, between the two populations didn't, so the quartiles, if you will, for the civilian population were -- early in the study, they broke at, say, two, four, and

eight.

By the eleventh year, they broke at two, three, and five approximately. The military population started at one, two, and three where the quartiles broke, and ended with breaking quartiles at one, two, and two.

So both declined, and this goes along with the clinical practice guidelines for getting people back into their normal lives as soon as possible, to include getting back to work, and that's the trend away from so much bed rest, so we could see this demonstrated in our study.

But the difference between the two remained, and so why were we making a point of this? Because some of these times off still appeared excessive. For some of these in 1999, 1998 claims, there were 45, 100 days off prescribed for nonhospitalized, just back sprain events. And, again, following the literature, that may not be in the best interest of that worker. It may be in their best interest to get, you know, back on their normal schedule of life, to include work.

So we guess that there may be a significant portion of civilian workers who could benefit from, let's say, more of the standard of

care.

As far as the day of week distribution, we found a -- I'll just cut to the bottom line there -- 61 percent increase in what we just called the post-holiday effect. This would be the Monday following a typical, non-government holiday week, or a Tuesday following a Monday government holiday, the odds were up 61 percent that it would have been post-holiday versus the other four days of the week in a full week or other three days of the Monday holiday week.

As far as the activities, they were absolutely all, again, the usual suspects, on and off duty. You couldn't tell, honestly, if you were reading some of these reports. It was people doing all these things, whether they were at work or not. So we'll jump to the discussion.

And from here, I would just like to present the discussion items of interest that are associated with our requests to the AFEB. And we see two huge opportunities for secondary prevention, and we propose doing a study to not only find these, but to also act on them.

To justify those beliefs in the study, I'll just talk a little bit about the FECA claims.

The last sheet in the notes is a cut-and-paste -I mean, I typed in from long data sheets FECA
claims by nature of injury codes. These are the
top nine nature of injury codes. They just happen
to be in order of Air Force costs for 1998. That
was the logic behind how these were ordered.

But as you see, for all departments and for DoD civilian workers, back strain was almost always number one or number two, at least for 1998, and if you look, you know, back to 1997, this isn't the case; other strain, contusions, and so on.

So there are a great number of claims per year and a great -- they pull a lot of dollars per year. When you do some of the arithmetic, however -- for example, in the back strain claims, only 3 percent of the dollars committed every year are associated with new claims, so 97 percent are cases that are older than one year, so you can imagine in just a heartbeat there the burden of disability claims.

Okay. So for our -- we would like to review -- of course, now you're wondering why we want to do an OWCP study, when I'm sure your primary interest is to look after the active-duty worker. This ties to the active-duty force, we

believe, for two reasons.

One, these dollars hog operational dollars for the line and the Air Force, so that's one right there. And the second is that the lessons learned from these studies will apply, because backache is something common to humans, not just to civilian workers. So the lessons learned from these studies, we believe, will apply, so those would be the justifications for going into the OWCP process. This is just a much tighter, more controlled group.

So we would like to look for -- we are guessing, with -- we are guessing there's two huge opportunities. One would be for case management, because this is less common in the military or OWCP system today, and we hope to, you know, find if there is a benefit for that, and then again act on it.

And then the second potential opportunity that we completely expect to find is that there is an excess of claims, not only for back strain but musculoskeletal events and job stress or mental disease that would be associated with BRAC. That's the base realignment and closure process.

For example, if Base X was bubbling along with so much of an incidence for so many years and then they come on the hit list, and a year before, all of a sudden, we expect to find the claims, especially the disabling claims, would climb. So we would like to model that excess and then turn that back into a cost benefit for a likely intervention.

For example, one idea would be, you know, as we know, these installation -- the BRACs are coming. Perhaps these specific sites could have an intervention, whereby there is a job transition process, where the workers could get modeled into another job, instead of realizing, Gosh, I have two years to retirement; I'm just going to, you know, do a disability claim, or whatever we find.

So those are the nuts and bolts of that, and I'll just open it up for questions and address more specific.

DR. LaFORCE: Questions?

MAJ. CARR: Yes, ma'am.

DR. SOKAS: Well, I guess these are more in the way of comments. One of -- I mean, on your last statement that downsizing clearly has a

major impact, not only on the people who are downsized out of a job, but on the survivors of downsizing, there's lots of information and a lot of research going on in that area.

I did wonder, though, whether there was any attempt to get at real risk assessment in terms of primary prevention. I think at one of these earlier meetings, we had heard or maybe you had even presented that the civilian workforce does most of the factory type work, and so there might be actual reasons for some of the increase in exposures, as well as outcomes, and that, for example, looking at whether the lifting index that's been recommended has been applied, whether there are actual ergonomic exposures that might be altered, you know.

And this doesn't seem to address any of that. And I'm just wondering what the --

MAJ. CARR: Oh, the study does, but those kind of -- as you say, those are kind of like no-brainer recommendations. Those will go out, and we don't believe there's a need for the Board to support them, because they should be universal. So they will have a bunch of primary intervention recommendations. We just focused on this for the

group, because we see the greater gain in dollars, if you will, on a secondary --

Supporting the study for the secondary prevention is a little harder, so --

DR. SOKAS: Well, that's interesting. You know, I mean, given OSHA's experience right now in trying to get an ergonomic standard put into place, that basically, you know, falls into the nobrainer category. I think it still would be interesting to collect that information and make use of that information.

MAJ. CARR: Yes. Absolutely. And the other thing that -- you know, we have all kinds of justifications for why primary prevention seems to fail, and some of the explanations are that, Gosh, when you look around the Air Force, there are a lot of installations that have excellent back care programs going on, and there are others that have good ergonomic programs going on, and they're all melted in.

We look at this, you know, all rolled up in one spot. There are definitely little sites that could do better and so on. But when we look at just the numbers and the figures, a lot of this secular stuff is lost.

DR. LaFORCE: Yes.

PROF. BAKER: I would wonder whether -incidentally, thank you for very nice presentation. In the military, it seems to me that there is opportunity for doing sort an controlled studies of interventions, which may be more difficult in the civilian world, to try at installations but not others, to ergonomic changes, because the --

I mean, there should be more emphasis on primary prevention, I suspect, than there already is, and you would have an opportunity to perhaps install, you know, assisting devices in some hospitals but not in others, and to actually study the effectiveness of primary prevention methods.

MAJ. CARR: Definitely agree. The database of the Army just released a study December of 1999, looking at disability and looking at their public health assessment data prior to claims, and found association with more of the new usual suspects, which are job stress, emotional stress, economic stress, and so on, that existed prior to them claiming disability, so it's certainly a challenge.

We have not explored the Air Force disability data yet, but these are some of the problems. The civilian is almost under better control for us to look at right now. The military workers' claims process is just harder to find, it's in so many databases, so --

DR. LaFORCE: Thank you, Maj. Carr.

MAJ. CARR: Yes, sir.

COL. DINIEGA: This is Col. Rice.

She's a special project officer for Gen. Peake, and she'll be talking about the back injury -- I guess, it's surveillance and prevention program that you're looking at. You can tell us what you do.

COL. RICE: Right. I didn't realize I'd be talking to the whole group. I was going to talk to the subcommittee, so I didn't bring slides or anything. I brought handouts. I'm not sure if there's even enough for everybody in the room, but perhaps you can share, and perhaps they can make copies if you would like to see those.

It's a special project for Gen. Peake.

It's really not on back injuries. It's on injury prevention as a whole.

Let me kind of give you some background information so you'll understand where he was

coming from and where we're coming from.

The project started -- Gen. Peake's very interested in injury prevention, and injury prevention, more specifically, in entry-level training. Well, we don't have entry-level training here at Fort Sam, but we do have AIT training.

And in his interest, obviously if he's going to have something done, it has to be within his area of purview, so we did a couple things.

Initially we did a couple of meetings. Col.

DeFraites is in the back, and he did the first one in IET injury prevention, and then he and I did a second one together with Keith Hooray [phonetic] at Fort Jackson on IET injury prevention meetings.

The second one was terrific. I don't know if very many people in here have heard about it, but that particular meeting was really nice, because we did surveys of line unit members, first sergeants, sergeants, commanders, and so we had not only their participation on paper, but we had them attend the conference, so we came up some really nice strategic initiatives.

Gen. Van Alsteen [phonetic] was also very interested and helped to host it, along with Gen. Peake, and that information then went back to

Gen. Van Alsteen, just before he left to TRADOC, and he took that information with him and the plans that he thought he could implement to TRADOC with him.

So out of that interest, then Gen. Peake said, Well, I really want to make some inroads on this, help make some inroads, and there's a lot of research being done, but I don't want research in particular done. What I'd like to do is see some programmatic action.

And he asked me if I could do something, and I said, I think I can do something, but obviously, it would have to be here at Fort Sam, because we just don't have the power to implement something somewhere else, and I need a staff and that kind of thing.

So this is what we took a look at here. For those of you who have this handout, if you want to take a look at it, you can see that we just went straight down with what we needed to do.

The first thing that we're doing here at Fort Sam is to assess the situation. What's going on? What exists at Fort Sam? What is a -- it's all musculoskeletal injuries, active duty only at this time.

Obviously we are involved with musculoskeletal injuries with civilians also from the ergonomic committee standpoint, but this particular project is dealing with active duty. So we went in and took a look at what musculoskeletal injuries there are right now. You may know from your posts, you can't get that information on any particular post easily.

If you look down through your slides, you'll see that what we did was we went into the Defense Medical Epidemiology database, and rather than using those large classifications, you know, like the 800 series for musculoskeletal injuries, we went down individually and picked out every single musculoskeletal injury that we thought was something that we could deal with, and then ran the statistics that way.

Now, what we found was, according to that data, 20 percent of all the clinic visits here at Fort Sam outpatient are musculoskeletal injuries, which is about what you'd expect in 11 percent of the hospitalizations, with the outpatients increasing over the last couple of years, last several years, and the hospitalizations slightly decreasing.

When we did an estimate, the estimated costs: 2.5 million for the outpatient visits here at Fort Sam, and I think that's pretty conservative.

The one thing that was difficult or that was not exactly what it needed to be is that this system takes ADS information and combines it with PURSCOM [phonetic] information, so that anybody who's here TDY doesn't get reported. And on an AIT site, we have an awful lot of people that are here TDY, and they are reported back to their parent post.

So although we have this information, it's not accurate, and it also doesn't give us very much that we can do with it yet. It doesn't have any cause data. We don't know how these people were injured, what the mechanisms of injury were.

have а slide that's kind interesting. Yours are not in color, but you can see -- what page are we on? Bottom of page 2, we have spent an awful lot of money on things like hypertension, diabetes, heart disease. These are ones that are low on that. You can musculoskeletal injuries, tremendous number of have we musculoskeletal injuries; three times, four times

as many musculoskeletal injuries as we do have respiratory illnesses. That's all respiratory illnesses here at Fort Sam.

So it is telling us the importance of it, but, again, there's nothing we can do with it, to target the interventions. So what we're doing now is we put together a surveillance system, several surveillance systems, in fact, and what we're doing -- and you're welcome to have copies of these.

We're doing surveillance at first entry into the medical system, so at the TMC, emergency room, and our adult primary care clinic. It's a short questionnaire; it's been approved by everybody at each of those facilities, as far as the medical personnel, and it's one page, front and back. Most of it's filled out by the patients themselves.

Obviously you want it to be really short, and it's short enough so that when they go in and have their blood pressure and temperature taken, they can fill it out at that time. It goes right into their medical record; medical record goes into the box for the doc, and then the doc or PA or whomever does fill out four questions on the

back. That's one survey.

The next survey goes to everybody who comes on post, when they first arrive, so we have that going out at one stop here at this post.

Everybody that comes onto post has to fill out the health risk appraisal. It's going to be given out at the same time that they fill out the health risk appraisal.

With our AIT trainees, it will be given out by their companies. And each of the companies was already doing an initial evaluation of people that came in, and so we took all the things that they were asking, combined it with what we're asking, and put it on to one form, and all the data will be scanned in.

The other two questionnaires we're doing is another one for everybody that goes on profile while they're here, and then everybody as they leave post. So we're going to have an awful lot of real-time data, to know exactly what's happening on post: who's injured, where, how, why, and who arrives injured.

One of the big complaints was that, We're not really injuring them here; they're all arriving from basic training injured. And that may

be true or it may not be true. We really don't know that, and so that's another thing that we're trying to gather the information. I know that quite a few of them do arrive injured, but we don't know exactly how many and we don't know from which posts.

It's important for us to be able to go back to those posts and tell them that. In the meantime, we're trying real hard not to make too many inroads in the actual programmatic portion, because obviously we want to be able to collect good baseline data before we start doing intervention.

The interventions we to want be targeted according to the data that we bring in, but we also know that there are going to be some interventions that are not targeted in that way. For example, in our companies, at least for the AIT groups for our brigade and battalions, what they're doing right now for their data collection for their entries is paper and pencil, the same way that they are collecting our data sheets for our PT tests. It's paper and pencil; it's not all computerized yet.

Also it's not big on their agenda as

accountability, so far from that as nice interaction that we had at Fort Jackson, we've gotten together with a couple of their commanders who are using some pretty good data management systems that are global, that are not just injury preventions, but they're everything a commander would ever want to know about his soldiers, and putting it into an Excel and Access database, so that they have a screen that can pop up, that they can see what's going on in their battalion or brigade or company at any time that they want.

And one portion of that was injury prevention, so we're working with them. They're coming down next month to help us work on putting a database system in here for our brigade that will be very similar to theirs. The idea is to change the contextual environment.

It will not only make them accountable, because that brigade commander, I mean, with the click of his button, can go all the way down to unit level and know what the percentage of injuries are, and many of you know Ltc. Henry at Fort Jackson uses this system, and he's described to me that he has a 3 percent rate that is his own rate,

that he doesn't want his battalion to go above.

Any company that goes above that shows up on his radar screen.

He goes all the way down to the unit level, finds out where it's happening, and then he goes down to talk to the people, to find out what's going on, what kind of injuries are they, why are they occurring.

And one of his descriptions was that he did this several months ago, and his estimation of what the problem was, was either I've got a first sergeant who's grand new and is not paying attention to the injury prevention, or somebody that's leaving and just doesn't care. And he just walked down, started talking, and found out that the latter was the case, but he tries very hard to make it --

Like I said, it's an organizational change, partially of accountability, but also of emphasis, so one of the other things that we're doing with them is helping them to, as a company, put this into their context through what we're calling a PT Advisory Committee.

And this PT Advisory Committee will consist of representatives from every company, and

the whole idea is just to get together and talk about what we can do to prevent injuries, while keeping the performance as high as it can be.

And it should be run by the company-level individuals with experts coming in to just kind of be there as consultants, so people from our Operation Aegis -- and if you don't know what aegis is, aegis was the shield of Athena. If you're under the aegis of somebody, you're under their protection or their mentorship, and that's what that means.

So we'll have representatives from us; we'll have physical therapists and physical therapy assistants, and a statistician that works with me; also have a dietician that goes down as a consultant, probably somebody from the BAMCI PT department, perhaps OT department also, and the dieticians are working closely with us in all that we do and some the questionnaires, all the way along.

So that's part of the contextual part.

We have a couple other thing that we're doing.

The shoe-fit program that many of the posts have;

we've got that on-line, ready to go, as soon as

we're ready to go with it. It's gotten enough

attention from what we've done that AAFES wants to do it US-wide, and so they've been with us and on our web site and talking to us about how to do it and what they need to do and how to put it in place.

Now, there's absolutely no data that shows that that does a thing, which is nice for us to know, but what it does do -- it's kind of like back belts. Back belts tell your people that you love them, you care about them, and that you're doing the best that you can, in spite of the data, because the research just isn't there to back it up.

So we've got that, at least in the plans. Stretching, the data on stretching, you've got part that says it's really important, and you've got data that says it's not that important. The situation hasn't been resolved academically yet, but we know that they're not going to throw out stretching, so that's another part of our intervention, is to go down and talk to them about what they are doing with their PT, what kind of stretches are they doing, what kind of exercises are they doing.

We all know that some of the PT

training, they're changing the documentation now. Some of the things that are there to do are actually not good for the soldiers, so we'll be down there working with them on that and going over their overall picture of what they're doing for training, not just their physical training as far as push-ups, sit-ups, and runs.

But what days do they march, and are the days that they go on these road marches the same days that they do aerobic activity? And do they have to march to and from class? And if they're marching to and from class, are those on the same days that they're doing aerobic activities, so that they may have overuse injury?

It's turned into a project that when I first started it, I thought, Well, this can't be that hard; we'll get in; we target; you know, we do these things. But I'll tell you the truth. The vast majority of the project is organizational effectiveness, and it's meetings with the commander and with the sergeant. And many of them, I can't go to.

The PT Advisory Committee, I can go in and I can stop it and I can check and see what's going on. But to have a colonel in there disrupts

the whole process. And so what you really need to do is we have to be getting from the ground up.

And I can see already that in another less than a year or perhaps a year, when we leave, if we've done our jobs correctly, the companies, the commanders, will go, I know they had that Operation Aegis thing; they had injuries -- you know, control injury prevention going on, but I really don't know what they did. We had this committee, though. We did this, and we did that group did.

And that's what's going to happen, and that will be really what shows that it worked, because we want it to be in the control, not of the medical personnel, but we want it to be in the control of the line personnel. They're the ones that are going to do it with just us being consultants.

The last thing that we're supposed to be doing with this project is writing it all down, in kind of almost like a textbook form: what we did, what worked, what didn't, so that any other post that wants to start a similar kind of a program can do so and have a step-by-step guide in

how to do it.

Are there any questions? If anybody has answers, we take answers.

DR. MUSIC: This is a breath of fresh air. This is just wonderful.

DR. LaFORCE: You know what this sounds like? This is, you know, continuous quality improvement in a decentralized way. I mean, you could be cloned and present this at IBM, Ford, or -- I mean, this is absolute contemporary management, which really resonates quite well, because it's very, very successful methodology.

DR. MUSIC: Instead of the plan that was presented to us, if every base had a clone of this lady, I think we'd be there.

DR. SOKAS: But, you know, I think one of the things you pointed out, though, was that you have real leadership commitment, and it sounded very similar to -- there's a fellow -- I forget his name -- who's head of ALCOA did the same things, came in, said, We're going to find out where we have our injuries, so there's data collection that's required. We're going to go after them, and we're not going to be satisfied with mediocre results. And it sounds like you've got the whole

loop there.

COL. RICE: That's absolutely right.

You have to have that top support, obviously, or you're not going to have the manpower and the personnel and the money to do anything. They also have to give you the freedom to do what you need to do.

And like I said, there's a lot of research going on, but there's really not very much programmatic implementation that's also tracked going on. And so we had to be given that from the top, but it also has to grow, like I said, right from the bottom. And to grow it from the bottom, you have to really kind of plant it from the middle.

DR. LaFORCE: Thank you, Col. Rice. Thank you.

should break up within the I want to point out. We really have subcommittee. in five tasks terms οf the committee responsibilities. The five tasks include response to the question about the military public health laboratory workshop recommendations, which is a clear-cut question.

The second are the questions on

tuberculosis screening policies and new technologies, which goes to disease control.

A response to the DoD injury/occupational illness prevention action plan, that needs to be a specific response to this particular action plan, as it was presented.

And, lastly, the final report regarding pyridostigmine bromide that we chatted about yesterday with Dennis Perrotta.

And also, lastly, a statement which I'll work on drafting, that has to do with the anthrax immunization program. So that's a fair amount of work. And what I'd like to do is break up now and reconvene at eleven o'clock, which gives the committees or members of the AFEB an hour and a half to sit down and jot your thoughts along those particular -- or in terms of these particular items for discussion with the general group at eleven o'clock.

COL. DINIEGA: What works very well is if you can draft at least the first draft of potential recommendations, and you can use the computer to project them, and I have some disks here that you can bring and load here and discuss it in the larger group.

The Environmental and Occupational Health will meet in 3305 upstairs; Disease Control will stay here; and Health Promotion, you'll meet a little bit and then you'll merge with some of the -- split up for the committees. And you can either do that in The Pit, or you can go to 3304 to do that.

And the participants are welcome to join in on the discussions, and you may be able to answer questions for the Board members on specific issues, so go to whichever subcommittee you want to go to.

Any further staffing and revision of draft recommendations can be done on e-mail, but at least try to get the basic structure and some of the main points.

DR. LaFORCE: Fair enough.

COL. DINIEGA: And then the executive session for the Board members and preventive medicine liaison officers, our next meeting is 30th and 31st, and if you didn't in -- of May, and if you didn't sign in, please sign in so we know who came to this session.

(Whereupon, the meeting was recessed for subcommittee meetings.)

DR. ATKINS: We felt that the goals of our committee were to focus on those health promotion, disease prevention issues that will have the greatest impact on the health of the military and their families, with the goal of maintaining a healthy and ready force, but also recognizing that there'll be long-term benefits of this.

And we thought the -- our goal was to help develop an effective set of priorities, both at the clinical and at the community policy level that relates to health promotion, and after some discussion, felt that the goals and objectives in Healthy People 2010, the recommendations of the U.S. Preventive Services task force, and recommendations coming out οf the parallel activities of the CDC Community Preventive Services task force, provided a good starting point for developing some priorities that were most applicable to the military.

And our recommendation is that we selected board members, work with the preventive medicine specialists in the individual Services, to have them present to us their thoughts on what the high priority services, again both community and at the clinical level, would be, starting with this

broader set, and also recognizing that there are important systems issues that related to information systems, other implementation issues that may be critical to making progress in terms of both clinical preventive services and community prevention.

And our other request is that we hear a status report at the next meeting on the -- those Service-wide priorities that have already been set on alcohol and smoking, where there are plans being developed.

That was it, and I will put that together and circulate it.

DR. LaFORCE: Okay. I'm going to ask more specific questions. When you said Board members working with individuals within service groups, how is that going to take place? By email, or is there a meeting that's going to take place? How's that going to take place?

DR. ATKINS: Well, that's what we were discussing sort of as we broke up. Dana, maybe you can help me, in terms of -- the feeling was we want -- we thought it was more effective to hear separately from the individual services about where they thought those priorities were, and we're happy

to communicate with them by phone and e-mail, to clarify exactly what we're looking for, the kind of feedback we're looking for from them.

DR. LaFORCE: But is there one time when you all come together and discuss your priorities?

COL. BRADSHAW: Well, I think -- and, of course, what we actually had thought -this could be maybe, you know, open for actually bring discussion -- was to those like we do with other priorities and some -disease questions or infectious disease questions, is bring things here to the Board with some background about why we might want to target a priority within our respective Services, and then have the AFEB give some direction on what they think the top five, for instance, things might be for us to focus on.

I mean, we have the Prevention, Safety & Health Promotion Council's list of three: alcohol, tobacco, and injury, which are a good start, but there may be other things that are unique to the military setting that it would be useful to help -- I mean, because we've got a lot of different efforts that are going on, and some of

them are -- there's a lot of effort being spent on things that may not give us enough bang for our buck, and it would be nice to have some direction from a knowledgeable, you know, source and credible source such as this, to help the leadership, you know, focus in on some things.

DR. LaFORCE: I was just trying to jump-start this. I'm sorry. I was trying to jump-start in terms of saying, if from now until the next AFEB meeting there is a subcommittee meeting or a time frame at which you're meeting that either David or somebody could go and -- you know, because what happens is then you really get a jump-start in terms of the next meeting, then the head of the subcommittee already is well informed in terms of this.

COL. BRADSHAW: Of course, all the preventive medicine officers are on the policy group, which I chair, and David's right there in town. We meet in town.

COL. DINIEGA: Well, I think the other way to go about this is I actually in my budget projections, project three general board meetings and three subcommittee meetings. The other way to do it is have the subcommittee meet and have the

Services come and present. That's another way to do it, so whatever is your desire.

COL. BRADSHAW: Well, I mean, whatever you think would meet the Service --

DR. ATKINS: So you're saying we could have -- our subcommittee could have a meeting in between our regular meetings and have the Services presented to us, and then have it filtered before it comes back to the whole Board.

DR. LaFORCE: Then that initial step has been taken, and I think it would be more fruitful in terms of interaction at the Board level.

COL. DINIEGA: For example, the immunization, the red book, was done with having, I think, two subcommittee meetings.

DR. LaFORCE: That whole thing?

COL. DINIEGA: The rest was done e-mail.

CAPT. SCHOR: The only other thing that Cdr. McBride and I just talked about was perhaps the benefit of having this as some sort of a formal request from the AFEB to the Services. That would help us as one-of's in many cases or, you know, to prioritize our day-to-day work, in putting together

a list and devoting the time for a thoughtful reply to your request.

COL. DINIEGA: We can do that. We can write a memo and say that the AFEB would like to hear the following, and Dave --

COL. BRADSHAW: Well, and plus, you know, from our perspective, thinking of health promotion, I think we're, all of us, are going to need to get input from our health promotion side, and we know certainly on the PPIP committee -- and I'm thinking Navy really can escort me and, you know, Dave McKay [phonetic], and the Army's got Andy Hemingway [phonetic] and --

CAPT. SCHOR: And I have Candace Courtney [phonetic] from the Marine Corps.

DR. LaFORCE: Okay. Could I -- either David and yourself -- we'll send something out, but actually before the -- I would very much like to see that, something happen in between, before the next meeting if we possibly could. Okay? Terrific.

Who's next? Stan, are you going to present?

DR. MUSIC: We have something printed out, to pass --

COL. DINIEGA: You can use the overhead, if you want.

DR. MUSIC: This is just a draft, and I will read it out. It's a draft cover letter. Our proposal, obviously, is that we accept the report as written, this Perrotta document, and we transmit it to Sue Bailey or whoever we have to send it to, with some version of this draft cover letter, and I'm going to read the cover letter now.

"Within the range of what we have come to expect over the years from the RAND reports and reviews, the second volume of the Gulf War series, dedicated to pyridostigmine bromide, is clearly an outline:

"No critical review of the literature, argued without balance and judgment, giving weight to a reasonable path in the face of conflicting but inconclusive data, essentially an indiscriminate catalog of what has been published;

"Use of news and Internet sources instead of being restricted to standard, peer-reviewed papers; especially problematic in light of the emotion around Gulf War illness;

"Recommendation for more epidemiological studies based on clearly inadequate

recall nine-plus years after the fact;

"No flag or explicit recognition of the over-arching issue;

"The quality and level of internal and external review that was performed is not apparent;

"Scientific recommendations made throughout the document are based on weak and unevaluated information.

"These shortcomings are so profound as to render the document scientifically too weak for us in policy development. Furthermore, the document itself appears to have added to the burden of military decision-making through person-hours spent in efforts to clarify the quality of this information. This represents not only a lost opportunity, but also wasted resources.

"This is unfortunate, but is an honest assessment of what we see in this report that is far less helpful than it could be.

"The attached subcommittee report details the AFEB's concerns with the RAND document. It also raises the over-arching concern of assessing efficacy. The AFEB would like to point out that efficacy considerations and side-effect profile should inform future decision-making on

this issue."

DR. LaFORCE: The gauntlet has been laid.

DR. SOKAS: How do you really feel?

 $$\operatorname{DR}$.$ HAYWOOD: That was the first version.

DR. MUSIC: Strong letter to follow.

DR. LaFORCE: Now, is this too harsh?

David?

VOICE: Well, you drafted it, David.

DR. PERROTTA: This is not my --

DR. LaFORCE: Okay. I actually don't like to fool around very much with these documents when they come out this way, you know, because sometimes they can be massaged and they're meaningless after they get so massaged, and I think if -- this certainly reflects, I thought, the general tenor of the AFEB's take on this particular report.

Is this correct? Am I -- is my perception correct?

COL. DINIEGA: Well, now, there is -- one caveat is that I think when this is -- this needs to go by the members who are not here also.

DR. LaFORCE: Fine.

COL. DINIEGA: Because all the members got the read-aheads; Coming or not coming, they all got the read-aheads. So I would recommend that it goes to all the members.

DR. HAYWOOD: I move that the cover letter be accepted in principle for further circulation and refinement.

DR. LaFORCE: Do we have a second?

DR. SOKAS: Second.

DR. LaFORCE: Second. Question.

COL. WITHERS: I have a comment. The real problem with the RAND report to the Department of Defense was really the conclusion that it could not be ruled out as a source of Gulf War illness. And you all haven't said a thing about that particular finding in here.

You have in general sense. You said, Well, the whole thing's sort of useless, and, you know --

DR. LaFORCE: Yes. But, again, this is simply a cover letter for this.

CDR. McBRIDE: You're suggesting that revisions need to make mention of that particular --

COL. WITHERS: Yes. I'm just

suggesting if you want to offer it, you might --

CDR. McBRIDE: In the letter?

COL. WITHERS: -- say that the real piercing arrow of the RAND report is not mentioned in the cover letter. Do what you want with that.

CDR. McBRIDE: And if they don't read the attachment, maybe you want to have mention of it in the letter.

DR. LaFORCE: Stan, would you feel --

DR. MUSIC: Be happy to.

DR. LaFORCE: Put that in, include that -- I think that's well taken.

DR. SOKAS: Wait, wait. What are we -- what exactly are we going to say?

DR. LaFORCE: No. The sentence will be more focused in terms of disagreement with the conclusion that was drawn from that tome.

DR. MUSIC: Where is that section in this report?

DR. SOKAS: In the -- in Dennis's report.

CAPT. TRUMP: My only suggestion there would be more in the tone as the -- short of doing your own review, you know, to argue the counter, what you're saying is much along the lines of

policy, is, This document is too weak to support changes in policy. My assumption is you also find it too weak to make the conclusion that the author had.

DR. LaFORCE: Yes.

DR. MUSIC: And we can add that; let's do that. And I'll circulate that.

DR. ANDERSON: Because we didn't review to rule in, rule out PB, and what our complaint was: The document doesn't do that either, other than to say you can't rule it out, but they don't really say why. I mean, going into it, you could have said, You can't rule it out. Coming out of it --

DR. SOKAS: See, I don't know if we can actually get -- since we didn't really --

DR. LaFORCE: So we can't what?

DR. SOKAS: I don't know that that extra sentence is something that -- I mean, I don't see it in the way this is written, and I don't know if we want to add stuff to what's been written here.

DR. LaFORCE: We certainly can. This is a draft final.

DR. SOKAS: I'm saying, I don't believe

we should.

DR. LaFORCE: Okay.

DR. SOKAS: Okay.

DR. MUSIC: Well, to the extent that we do not like this report, that this report is far less useful than it could be, we can also add the sentence that we cannot support the recommendations.

DR. SOKAS: Well, I think that's in that cover letter. Okay. All right. That's fine.

DR. MUSIC: No, it's not explicitly in there.

DR. SOKAS: Good enough.

COL. BRADSHAW: I think maybe what Col. Withers is trying to get at is sort of like what I said the other day. To me, it seemed to be a departure to try and imply that you haven't proved a negative, saying you can't rule out, because you can say that about virtually any --

DR. LaFORCE: Yes.

COL. BRADSHAW: And the research could almost never be done on this. I mean, I don't know. It just seems like a departure.

DR. SOKAS: See, I'm a little concerned that if we do too much along those lines, that

it -- well, that the purpose of this cover letter and of this report is to torpedo this document, but you don't want to make it look like a partisan torpedoing, and I'm a little afraid that that could do that.

COL. DINIEGA: Well, you know, one is -- I get the sense the committee accepts the report, except for the apostrophe or whatever the change was. And the cover letter should state that it strongly endorses, and then any other comments that you want to make, that is in keeping with the spirit of the document.

COL. BRADSHAW: There was one thing in the report that I'm sorry I didn't get to comment on this morning, but there was one sentence that, standing alone -- I agreed with pretty much everything that was in there, but where it stood alone was the first time that you talked about no additional research based on the --

It says, page 3, "The committee strongly recommends that no additional epidemiological studies of Persian Gulf War veterans be supported or performed."

CDR. McBRIDE: We noted that in our subcommittee as well.

COL. DINIEGA: And I think they intended to say, Based on recall.

COL. BRADSHAW: Right. So I would just add that phrase, so it doesn't stand alone and get taken out of context.

DR. LaFORCE: Steve, this was your point, too. That's on page 3, the last paragraph.

DR. MUSIC: That's what the bullet that I -- the third bullet: "Recommendation for" -- I mean, this is a problem. "Recommendation for more epidemiological studies based on clearly inadequate recall nine-plus years after the fact." So that's -- I can expand that a bullet, if you want.

DR. LaFORCE: No. They just want it in the document itself, just say, Based on recall.

DR. OSTROFF: The document, as it currently reads, says, Don't do any more epidemiological studies, period.

DR. MUSIC: Based on --

DR. OSTROFF: No. It just says period.

DR. PERROTTA: It just needs to be clarified in the document.

COL. DINIEGA: Have you got that, Stan?

DR. MUSIC: Where in the document?

COL. DINIEGA: Page 3, bottom --

DR. LaFORCE: Page 3, last paragraph, Stan.

DR. OSTROFF: The very first sentence under, Specific Research Questions.

COL. DINIEGA: So what's the change?

DR. LaFORCE: Based on recall.

DR. SOKAS: But what it's saying --

DR. OSTROFF: Or based solely on recall.

COL. DINIEGA: Is that acceptable, the undocumented exposure, based solely on recall or undocumented exposure?

DR. LaFORCE: Just say, solely on recall.

COL. DINIEGA: Only solely on recall?

DR. MUSIC: Based solely on recall.

COL. DINIEGA: Okay. Where's that other change, Prof. Baker, the apostrophe?

DR. MUSIC: The apostrophe's on page 3.

COL. DINIEGA: You got that one.

Right?

DR. MUSIC: Yes. I got that one. Page 6, the neuro-transmitted disregulation, the last sentence, fifth word from the end, no apostrophe.

CAPT. TRUMP: One other minor one, the

top of page 4, the subheading, first subheading as capital P, small b.

DR. OSTROFF: Then the other one that I mentioned was in the second paragraph in that section, where it says, primates. It needs to say, nonhuman primates.

COL. DINIEGA: Second paragraph in that section.

DR. OSTROFF: Right. It says, "While the use of animal models is problematic, the human subject issue described above suggests that testing of PB treatment in nonhuman primates" --

DR. MUSIC: Okay. Good. Could I get the text of this either on a disk or sent to me by e-mail.

COL. DINIEGA: We'll do that.

DR. MUSIC: I'll dress it up, and I'll send it back to you for you to send it to the whole.

COL. DINIEGA: Got it.

CDR. McBRIDE: One question: The opening sentence on this draft cover letter says that, We have found the RAND reports -- I guess, apparently you're making the statement that typically they're pretty good, but this one is an

outlier.

Is that true? Do you feel that the RAND reports generally are really good, and that this is really a departure from the quality of previous RAND reports? I don't have a good idea of those.

DR. LaFORCE: In my experience, that's a true statement.

CDR. McBRIDE: Okay.

DR. LaFORCE: I think, in general -I've not read all RAND reports, but the ones that
I have dealt with, I thought have been well done.

DR. SOKAS: And they have a good reputation. I mean, it's not like a fly-by-night outfit.

DR. MUSIC: We have one other glaring error on the cover page. It says, Volume 3 in the title, and it should be Volume 2.

DR. SOKAS: Oh, dear.

COL. BRADSHAW: I would say that I think the -- my comment, I think, was on -- I don't remember if it was on nerve agent. I think it was another RAND report on nerve agents, that they included a particular rumor about a Russian nerve agent that was totally based on the Internet

article, and I know there was some Internet references in this report as well. But that was actually, I think, another --

DR. MUSIC: Well, we may want to --

COL. BRADSHAW: Yes. You may want

to --

DR. MUSIC: -- be sure.

COL. BRADSHAW: I mean, there are some Internet references in here as well.

CDR. TEDESCO: A minor point on what Cdr. McBride said: On that first sentence, if we truly do feel that the RAND reports are good and have a good reputation or whatever, I would state that explicitly in that first sentence. Given the excellent reports or whatever, rather than -- it's kind of implicit, based on the following comments, but you're saying it's an outlier, but you don't know if it's an outlier because it's good or from bad, if you just take that first sentence on its own.

DR. ANDERSON: This was meant to address the issue. We really haven't done a review of all the reports, so we kind of say, within the range. Sue was saying that some may have been good and some may have been bad, but even in the bad

ones, this is --

CDR. McBRIDE: But you typically expect --

DR. ANDERSON: Yes.

CDR. McBRIDE: This is beyond what you expect.

DR. ANDERSON: Right.

CDR. McBRIDE: And it's a real concern.

DR. LaFORCE: Are we ready to take a --

DR. ANDERSON: Right. So we don't -it's kind of damning with faint praise a little
bit, by --

COL. BRADSHAW: I mean, you have testimonies before Congress in here, Internet stuff, and it's supposed to be review of the scientific literature, so it's not necessarily peer-reviewed, so --

DR. ATKINS: To clarify the issue, the issue is not that their conclusion that the evidence cannot rule it out -- I mean, that's technically correct. The problem is that the whole tone in which it's laid out is to be much more suggestive than we feel the evidence implies, so it's unfair -- they could see it as unfair when we

in the summary say it failed to justify ruling PB

out or ruling it in.

The fact is that's the state of the data. It's just that everything else in the summary made it easy for people to feel like there's actually a very suggestive database here, even though it's not -- when in reality, we didn't feel that to be the case. So I guess don't know whether in the summary we could say, Well, their conclusion is technically true, that the data are insufficient to rule it out.

DR. LaFORCE: That's giving too much credit.

DR. SOKAS: See, I would leave that sentence off, then.

DR. ATKINS: I think the fact is, as Dana pointed out, you've got lousy data. You can rule it in or rule it out. Our problem is that they gave much more credence to lousy and speculative stuff. They didn't, at the end, say, We believe it, but they gave more credence to it than it deserves.

DR. MUSIC: But the first paragraph of our summary, page 7 -- read that. Let me read it.

"The special subcommittee of the AFEB reviewed the RAND document on PB, as well as brief reports of

DoD-supported research on PB. The report was found to lack critical evaluation of available data.

"Without professional judgment to prioritize current knowledge, the subcommittee found the report to be of limited utility. It failed, in our opinion, to justify ruling PB out as a cause of illness in Persian Gulf War veterans or to justify ruling it in."

DR. ATKINS: Well, I don't think any report could have done that, but it failed to help us decide --

DR. MUSIC: It couldn't rule it in, but it could justify raising it as a probable cause. I mean, it doesn't do anything.

DR. ATKINS: Well, maybe that's the wording, something --

DR. MUSIC: It's just a catalog.

DR. ANDERSON: It doesn't add to the understanding.

DR. ATKINS: Right. A good report could not have ruled it in or ruled it out, but it could have given us a better sense of whether this is worthy of further -- you know, whether this is worthy of further investigation or what specific issues are --

DR. MUSIC: Okay. Well, I'll work with everybody, until we get final words that everybody is willing to sign off on, and then we'll send it.

I'll take Dennis's place, so that this -- I'll be the coordinator.

DR. LaFORCE: Does anybody have fundamental --

DR. ANDERSON: The only other issue is, since this is relatively critical and they -- you know, it sounds like they would like to have come to the meeting, is it worth sitting down with them, to share this with RAND in advance or not?

DR. LaFORCE: Good point.

DR. ANDERSON: I mean, are we now going to get into a tit for tat? They'll feel this challenges their whole credibility and their ability to have contracts and all this. This is a big deal. Do we want to give them a forum, not that we're going to change our mind, but to -- you know, some of these they could view -- if I were in their spot, I would say -- I would try to build my case that some of these are cheap shots.

The basic underlying things --

COL. BRADSHAW: I would think they might want --

DR. MUSIC: That's why we say, we'll -there is -- "This is unfortunate, but it is an
honest assessment of what we see in this report."

DR. LaFORCE: Wait a second. This report's already been released. You know, you talk about -- come on now. Fair is fair. How can you blindside somebody when the report's already been published?

DR. MUSIC: Okay. I --

DR. SOKAS: But what was the question?

Apparently someone was invited to participate at the last minute and couldn't. What was the discussion around that?

COL. DINIEGA: What ended up happening is back in early winter, as our report was forwarded, the draft report, and it was also stated at the same time it would be up on the agenda for the next meeting in February or March, an offer was put on the table to invite the author to the meeting.

And then last week when I was talking to Dr. Cirone, I said, I did not hear anything from the RAND personnel attending. He then checked with OSAGWI, because he had given that invitation over to the Office of Gulf War Illness, and apparently

the ball was dropped there, and --

DR. SOKAS: So they never got --

COL. DINIEGA: They got the word on Thursday or Friday, and they said they couldn't make the meeting. They made an offer to -- they said they would have liked to be here. And then they asked if they could get a draft report.

You know, there's pluses and minuses.

Dialogue is good, but they published their report,

and I don't think the Services had any input into

the final content of the report.

COL. BRADSHAW: We had a chance to coordinate on it, make comments, you know, in draft, but, I mean, they either get incorporated or they don't.

COL. DINIEGA: Right. So --

DR. ANDERSON: That's fine. I'm comfortable going. I just --

DR. LaFORCE: No. If the committee wishes either Stan or myself or yourself could call her and, again, after it's been massaged and simply send a courtesy copy to them early on, I don't have any problem with that.

COL. DINIEGA: So the plan would be when it's final but hasn't been fully accepted, to

go ahead and send them a draft of the final and say, This is what's going to go forward to Dr. Bailey. And not ask for comments back, because you're not going to -- you shouldn't change what you're going to write.

DR. ANDERSON: We're not going to change.

 $$\operatorname{DR.\ MUSIC:}\ I'll$$ be happy for you to do that when I tell you that --

COL. DINIEGA: When it's ready to go.

DR. MUSIC: -- when it's ready to go.

DR. LaFORCE: Okay. All in favor, in terms of the spirit of the discussion.

(Show of hands.)

DR. LaFORCE: Okay. Fine. Thank you.

DR. ANDERSON: And our other task was to come up with -- to address the issue of the injury/illness prevention plan, and we ran closer to the end, so I didn't get it typed up. But just to give you a general overview of what our discussion was and our key points is we came up with six key issues.

Number one would be a statement that AFEB has longstanding interesting and member expertise in injury and occupational health, and

we'll encourage the DoD committee to continue to seek AFEB advice via the subcommittee, and that we stand ready to provide constructive advice.

And number two was including occupational illness in the prevention plan has the potential for confusion as the current plan is exclusively focused upon injury prevention.

Then the plan contains many excellent elements, but lack of detail and the slipping time lines are symptomatic of the lack of dedicated resources, both staff and funding. The plan needs to be translated into a detailed implementation plan with time lines, assigned responsibility, and budgets.

Then the AFEB encourages an emphasis on surveillance, data collection, and the essential integration of safety and health data. Effective injury prevention requires a partnership between safety programs and health care. Shared data is a priority.

There is a need to review the plan and identify over-arching DoD policy issue gaps and separate -- and identify actions needed that are separate from programmatic and infrastructure implementation plans.

Then, lastly, the best practice's effort is essential and a priority which will require long-term resource commitment.

Committee members? Susan?

PROF. BAKER: I think that pretty much -- I'd like to see, you know, a copy of it.

DR. ANDERSON: Yes. I will type this up. I guess we're looking for if anybody has any other comments regarding this.

DR. LaFORCE: The main thing from my standpoint was the funding issue. We kept talking about that it just so cripples this initiative without --

DR. OSTROFF: If this is ever going to go anywhere and if they're really --

DR. LaFORCE: -- because it's going to need support --

DR. OSTROFF: -- serious about it, there's got to be some --

DR. LaFORCE: -- and it's either going to go or it's not going to go.

DR. MUSIC: It doesn't have to be as big as Global Emerging Infections, but it needs --

DR. LaFORCE: It's got to be something.

DR. MUSIC: -- a dedicated resource.

DR. LaFORCE: And the recommendation from the AFEB would be that that happen. I mean, I want to make sure that there's a specific recommendation to fund this, in terms of developing --

DR. OSTROFF: Well, and also that there be dedicated personnel to move the process forward. You can't have it sort of somebody doing it in their spare time and expect that it's going to move forward in any meaningful way.

COL. DINIEGA: It has a critical aspect to it. Everybody on that committee is making room on their schedule.

COL. BRADSHAW: It's a fundamental problem actually, to tell you the truth, of the way the entire Prevention, Safety, and Health Promotion Council is set up, because even the council itself is advisory to the rest of the DoD, even though they're very high-level people there, but they can do moving and shaking. But it doesn't have its own budget.

All the subcommittees, you know, are people that have other jobs in their real life that are working on this. It may be their area of focus, but it's good and it brings high-level

attention to these things, but there's no way to resource directly or to task directly.

DR. ANDERSON: So how about if I will summarize kind of that's our discussion, and then say, The AFEB -- have one recommendation; say, AFEB recommends that DoD provide dedicated staff and the necessary funds to implement the plan.

DR. LaFORCE: To develop the plan. You can't implement -- this one is unimplementable until it's developed.

DR. ANDERSON: Develop and implement.

DR. LaFORCE: Right.

DR. SOKAS: I think all of those points that you made actually could be couched as recommendations. I don't think it's one or two recommendations; I think it's all of them, but that's the first one.

DR. ANDERSON: Yes. Okay. So I guess what the committee -- subcommittee would be looking for is general agreement with this. I will type it up, get it to Ben; we'll circulate it again. Ben can maybe put it into a format that --

COL. DINIEGA: I'll put it together.

DR. ANDERSON: And so we can get it out before the next meeting.

DR. LaFORCE: Okay. Very good. Thank you.

DR. ANDERSON: I make that as a motion.

DR. SOKAS: Second.

DR. LaFORCE: All in favor.

(Show of hands.)

DR. LaFORCE: Okay. The last is the Disease Control Subcommittee. The Disease Control Subcommittee had three questions to look at. The first were the specific questions that related to tuberculosis. And then the second had to do with the review as far as laboratory-based surveillance, and the third, about anthrax vaccine.

And under t.he tuberculosis recommendations, there were some specific questions that came up. One had to do with specific cut-off recommendations, you know, the 10-, 15-millimeter after the PPD, and that one of the issues is that we did not have all of the characteristics from all the Services, that is, οf the Army, Marines -- the policies. And these will be pulled together, and from that, we would hope to derive a common cut-off recommendation policy.

Under optimal frequency, that is, frequency of repeat tuberculin testing, there was

actually a lot of discussion, and a sense that -and what we will -- or Steve and I will do is after
we've looked at the individual Service practices,
is try to harmonize the screening practices, or at
least if there's some way of harmonizing the
screening practice across the Services.

The two main sources that we were going to use were those published by the CDC and also the American Thoracic Society. The ATS has had a longstanding interest in this, and Lee Reichman [phonetic] is the individual that we would use to sort of help define items 1, 2, and 3.

With the question about two-step testing, we felt that there was no role for two-step testing in the military. And quality assurance issue, we felt was very important, and that this was an area that we probably would put up to the top of the list.

And the quality assurance related specifically to the issue of chemo-prophylaxis, particularly as the fraction of young recruits coming from other countries, other than the United States, or born in other countries other than United States, and who come into the Service with as high as 20 percent positive PPD rates, these

individuals are already infected and are at risk for developing cavitary tuberculosis at rates much, much, much higher, and the issue of quality assurance in terms of making sure that chemoprophylaxis is done comprehensively and appropriately.

We were going to suggest the issue of observed treatment, given that under the new treatment protocols that have been looked at in randomized controlled trials by the American Thoracic Society, there's now observed treatment with only two treatments a week. So it's not observing pill-taking five days a week or seven days a week. They've got it down now to two days a week.

Yes.

CAPT. SCHOR: Does quality assurance get at the issue of reverifying a positive PPD with a provider, rather than taking the report from the field as they get referred from an aid station or a corpsman, and bringing that back in to a fixed treatment facility and reverifying that?

DR. LaFORCE: That's a good question; that's a superb question. And we did not discuss that.

DR. OSTROFF: It's an interesting question. The problem is, can you do it realistically, without having to repeat the skin test?

CAPT. SCHOR: I just wonder how many times I started people prophylaxis, trying the reported results.

DR. SOKAS: The other thing was that the case we heard yesterday wasn't a disease case who needed directly observed therapy. It was the issue of prophylaxis directly observed. That person had spit out their prophylaxis basically.

DR. LaFORCE: That's what we're talking about.

DR. OSTROFF: Directly observed prophylaxis.

DR. SOKAS: So they're directly observed prophylaxis?

DR. LaFORCE: Oh, yes.

CAPT. SCHOR: Twice a week, and that can be done in many settings.

DR. LaFORCE: Yes. Ben?

COL. DINIEGA: Two comments. One, on the two-step, it says, No role in the military.

Does that need to be further specified, general --

COL. BRADSHAW: Yes. I'd like to ask a question about that, because at USUHS, when we looked at this with medical students, we decided to do two-step testing, because we were most interested in those -- I mean, not that we wouldn't have prophylaxed the ones that we found at first, but we also wanted to identify if they had been exposed sometime during their training.

DR. LaFORCE: Well, that's a research question.

COL. DINIEGA: Well, what about in the occupational health setting? Health care workers --

DR. LaFORCE: Well, the only individuals that we would see from a clinical basis that require two-step testing would be individuals who are immuno-suppressed or above 60 years of age.

DR. OSTROFF: Even your health care workers are going to have baselines.

DR. SOKAS: But the health care workers, the current recommendation in -- you know, that's being debated, so there's a debate about it. The occupational health community believes the baseline two-step testing, because of an increase in people over the age of 40 and foreign-born --

DR. OSTROFF: Yes. But the thing is --

DR. SOKAS: -- who are coming in.

DR. OSTROFF: -- we're -- I mean, all recruits here -- you know, you don't have that many recruits that are over the age of over 40.

COL. DINIEGA: Well, but you should specify.

DR. SOKAS: No. But 20 percent or 10 percent.

DR. LaFORCE: Okay. We will specify that. We think that the issue of two-step testing is not an issue in terms of accession.

COL. DINIEGA: Okay. Then it should be stated.

DR. LaFORCE: We will make that statement. And, of course, two-step testing is appropriate when the clinical indications are appropriate for two-step testing. Would that be a better --

COL. DINIEGA: Yes. That would be a better way to say it.

DR. LaFORCE: Okay.

COL. DINIEGA: And then the other recommendation is quality assurance be defined as to which quality program it is applied to, because

there's the issue of applying PPD; there's the issue of prophylaxis and observed therapy.

DR. OSTROFF: Right. There's no question that there needs to be more quality assurance, because I think that there's good documentation into the fact that there are problems.

DR. LaFORCE: Okay. Wе had some difficulty in of the whole terms issue deployment. And the difficulty was as follows: that deployment in countries with the tuberculosis risk as being in the United States, for example, should not be defined as a risk.

And what we were going to propose is using WHO, their tuberculosis risk stratification, much along the same lines as the global picture that was shown in the presentation, that we identify those countries or those areas, particularly Korea, the Pacific, that are known to be very high-risk areas, at which point, we were unable to resolve the discussion as to whether there was an obligation post-deployment to retest individuals.

And under the current -- for example, if -- correct me if I'm wrong, but I thought there

was post-deployment PPD testing if you were deployed to a high-risk area in all -- for persons in the Army. Is that not correct?

COL. BRADSHAW: The Joint Staff recommendation on deployment surveillance says that everyone has to have a TB baseline within two years of deployment and within one year of return from deployment, regardless of where that deployment is. It doesn't make sense.

DR. LaFORCE: And this was -- our point is that it didn't make sense, regardless of where it is, because if it's in an area where the risk for tuberculosis equals that in the United States, then those individuals ought to be caught up simply on a periodic PPD testing, and whether that periodicity is four years, as it was in the Coast Guard, or three years -- I believe it's three years for the Army --

COL. BRADSHAW: Well, what has --

DR. LaFORCE: What's your preference?

COL. BRADSHAW: -- become is de facto two years in the Air Force, because of the Joint Staff recommendation.

CDR. McBRIDE: For deployers, though, not for routine.

COL. BRADSHAW: Well, I mean, the logistical implications that some people have taken to say, Well, it's just easier; let's just do it -
DR. LaFORCE: Just do it every two

years?

COL. BRADSHAW: Right. Yes.

CDR. McBRIDE: The other thing that you expressed some criticism of, Dr. LaForce, was the Army policy, if I may, was that a routine PPD be done when they take orders overseas, regardless of what country they go to or come back from, and that perhaps that needed to be looked at.

DR. LaFORCE: What we will do is -- why don't you -- let us have a chance to wrestle with us, to see --

DR. OSTROFF: I mean, one of the issues is if somebody has an overseas tour to Mildenhall [phonetic] or someplace like that, I mean --

COL. DINIEGA: I think you've got to address it in two ways. One, you've got to make a statement about TB screening for deployments, and then you've got to do one for TB screening to -- assignments to -- PCS and assignment to countries with high risk.

DR. LaFORCE: Okay.

COL. BRADSHAW: And let me make one other comment on another one that has already disappeared above, but the cut-offs issue, when you say use of CDC cut-offs, the problem we've had is some people -- the cut-offs are based on risk status.

DR. LaFORCE: Correct.

COL. BRADSHAW: But it doesn't specifically answer the risk status of deployment, and what some of our people have done is they've interpreted deployment, regardless of where, as being high risk for conversion and, therefore, you should use a 10-millimeter cut-off rather than 15.

And so that's a problem, you know, in trying to get people -- you know, my opinion is that really it probably should be 15 for almost our people.

DR. LaFORCE: Well, one of the difficulties that we have is that you can set up again an algorithm with a lot of different arms which says, Well, it's 10 millimeters, but if you went here, we'll make it -- I mean, it's 15, but --

DR. OSTROFF: But nobody can follow it.

DR. LaFORCE: -- if you were here, we'll make it 10. And then you end up with somebody saying, Well, was the full moon out; I

mean, does this really count. And so what happens is the recommendations may be accurate, but they're not street smart. They're not street smart, in that they're not implementable in a regular sort of way, that misses the public health question.

You know, it may be technically correct, but doesn't have any public health relevance, and this is the question that Steve and I were sort of wrestling with.

DR. OSTROFF: My gut instinct is that there's too much --

COL. BRADSHAW: Yes. And that's --

DR. OSTROFF: -- testing being done now.

COL. BRADSHAW: I mean, if we're looking at actually what the burden of disease of tuberculosis is in our population, we should err on the side of being, you know, maybe less sensitive and more specific.

DR. OSTROFF: I agree with you.

DR. LaFORCE: And as we were having our discussion, we felt that the major risk to the military now, particularly the Army, was the recruitment of individuals who are skin-test positive at the time they enter the military. That

is, I think, the most important risk, given all the epidemiologic data, which shows very little tuberculosis, frankly, within the military.

However, with the difficulty in recruiting and the fact that you're now recruiting a different pool of individuals, one out of five are PPD positive. They are going to break down unless there is appropriate chemo-prophylaxis that's given to those individuals, and that was why we kept going back to this QA, and accession is the most --

DR. OSTROFF: I would say in accession you want to have a sensitive way of detecting people who may be infected and when coupled with the ability to actually deliver the preventive therapy, and that after that, I would advocate less frequent screening, but in a circumstance where you would have high specificity.

CAPT. SCHOR: I'm not sure how this may help or hinder those of us in big gray boats, and that issue there, if I can ask --

DR. OSTROFF: Well, we think the big gray boats are a special setting.

DR. LaFORCE: Yes. We think the big gray boats ought to be once a year. We think the

big gray boats are a risk. And we think that the current recommendation for annual skin testing is, we would say, entirely appropriate.

CAPT. SCHOR: So you would suggest supporting that?

DR. LaFORCE: Oh, yes.

CAPT. SCHOR: Thank you.

DR. LaFORCE: Priorities for future research: The QuantiFERON question, we felt that the data were not persuasive enough to think about shifting to QuantiFERON versus the tuberculin skin testing. However -- at this time. However, there's a great deal of interest in this, because if this were to pan out, this could simplify a lot of things, particularly if it increased sensitivity and specificity.

However, we felt that the data, as all of us discussed at dinner last night, during the course of yesterday, just weren't strong enough to make that recommendation.

We then went back to the people from -
I forgot the laboratory --

CDR. McBRIDE: CSL.

DR. LaFORCE: -- CSL and were discussing with them in terms of we're very, very

interested in the group that were skin-test negative and QuantiFERON positive and vice versa.

What happens to those two pools, because if there -- if this is real and it's a more sensitive test and some of these individuals do develop tuberculosis who were QuantiFERON positive and skin-test negative, then that might be a very, very important step forward, in terms of being able to screen and being able to identify those individuals that were --

DR. OSTROFF: My gut instinct is that this is actually a good test and that I think at some point, probably we will end up gravitating over to the more widespread use of this test, but it just isn't ready yet, to make that sort of a decision.

DR. LaFORCE: But we think probably -- the follow-up for the Kenya study was going to be at least another year or two, and so I suspect that within a couple of years, we'll be back with more data. And from our standpoint, at least AFEB, we still remain very interested in this, because we understand the logistic difficulties that are involved with skin testing.

CDR. McBRIDE: Would you say that even

for the Reserves, for instance, that it's still not ready for prime time?

DR. LaFORCE: Not ready for prime time.

DR. OSTROFF: Absolutely.

DR. SOKAS: Also, like the Kenya study, the follow-up for the Great Lakes study, if it could be accomplished, those 170 or whatever they were PPD-negative, QuantiFERON-positive people would be really good to get their one-year follow-up.

DR. LaFORCE: Yes, David.

DR. ATKINS: Can you tell me what the rate of progression -- what's the average rate of progression to active TB in a --

DR. LaFORCE: It's about 15 percent.

DR. ATKINS: Over what time period?

DR. LaFORCE: Two years.

DR. ATKINS: Over two years?

DR. LaFORCE: Yes.

DR. OSTROFF: After conversion.

DR. LaFORCE: Yes.

DR. ATKINS: After conversion. Okay.

But --

DR. OSTROFF: And most of that risk is within six months of conversion.

DR. LaFORCE: And so you would expect -- the numbers in some of those groups were like 150. I mean, they were big enough so that you'd expect to be able to find cases.

DR. SOKAS: Well, cases, and also it's two-stepped. By the time they come back for their annual follow-up -- I think those people have an annual follow-up -- then you would expect to see your boosted two-step response, if -- you know, in at least a proportion of those.

DR. ATKINS: But the assumption is that difference between the 2 percent PPD positivity and the 7 to 8 percent QuantiFERON is not 6 percent new converters; it's -- if those are all true positives, they might have been old infections.

DR. SOKAS: Right.

DR. ATKINS: So you might --

DR. LaFORCE: Right. Or individuals who are in the process of converting over. I still am not sure.

DR. ATKINS: Right. But I'm just wondering whether we have enough -- I mean, is 150 enough to expect to see a progression to active TB?

DR. SOKAS: I'm not so sure about that part, but I would expect to see a fair amount of

boosting, you know, that if these were old cases,

I would bet a quarter of them are going to show up

on a two-step a year later, as --

DR. LaFORCE: The next time they're --

DR. SOKAS: The next time they're screened, they'll be positive.

DR. LaFORCE: Now, what happens if the next time they're skin-tested, they're negative?

What do you think about the QuantiFERON then?

DR. SOKAS: I think it's information.
Yes.

DR. LaFORCE: Okay. In terms of research activities, we think that's a dynamite, that that whole QuantiFERON and the continued follow-up with these individuals is a terrific research project, which all of us would be in favor of seeing continued.

Next. That's it?

COL. DINIEGA: There was considerable -- Dr. LaForce, there was some considerable discussion on the economic analysis.

DR. LaFORCE: Yes. And in point of fact, before we would go very much further in terms of the economic analysis, I think the question is, one: Is this really going to be worthwhile? And

once it's worthwhile, then actually sit down with the economic analysis. It actually looked pretty cheap to me. In other words, it looked like the costs were a bit lower than we would have anticipated.

COL. DINIEGA: So do you want to make a statement about the economic analysis should be redone, should be relooked, once the QuantiFERON --

DR. LaFORCE: No problem. Excellent. Yes.

DR. OSTROFF: We can put that in; that's no problem at all.

DR. LaFORCE: Okay. Under the public health lab discussion, all of us were very favorably inclined towards a general positive of this, in of statement terms laboratory-based surveillance activities for the military, linking all of these together. And the only recommendation was one of general enthusiasm for this entire project as being a very sound investment of resources and as long as feedback was part of the entire process, something that was likely to yield great dividends.

In terms of anthrax vaccine issues, there was agreement that the AFEB should make some

sort of policy statement, and we're going to draft that policy statement, emphasizing that the activities, in terms of the ACIP recommendations that are now in draft form, about use of anthrax vaccine, that there is already a great deal of oversight in terms of the safety and that we feel that the activities, in terms of the press and other groups have not been terribly helpful, and that this is a safe vaccine, a licensed vaccine, which is being used appropriately.

We were very concerned about a potential shortage of the vaccine and felt that individuals who are likely to be at risk ought to have preference for the use of vaccine if there is a vaccine shortage; that is, individuals assigned or if they are likely to have duty in Iraq or anywhere near there have got to have preference for the vaccine, rather than finishing a course of vaccine for individuals that are likely to be based here in the United States. In other words, those at greatest risk have got to have, we think, access to that vaccine on a priority basis.

We know that with the use of anthrax vaccine, because it's a killed vaccine, if there's delay in receipt of doses four, five, and six, it's

really not that big a deal. You don't start over.

It's a killed vaccine. You just sort of delay the next doses of the vaccine itself.

The group was also -- was strongly supportive about continued activities in terms of resolving this vaccine production issue. It's an important issue and deserves the greatest degree of attention possible, so that these issues, as far as vaccine shortages, should not be part of general discussions.

DR. OSTROFF: Right. And then there was also --

DR. LaFORCE: What else was --

DR. OSTROFF: Well, the vaccine centers of excellence, there's very strong support towards the development of such vaccine centers of excellence, where you can really, very intensively, proactively and prospectively monitor side effects of not only anthrax vaccine, but a whole variety of different vaccines that are being administered in military settings.

And it's also the perfect setting to look at new vaccines as they come on board, in terms of the side effect profiles, so that you can sort of get ahead of the curve, of always being in

a position where somebody says that there's a problem, and then you don't have an opportunity to really have the data at hand.

And this is an excellent way to potentially do it, that it's simply unacceptable anymore to use passive systems, to think that you're going to pick up problems in that way.

COL. DINIEGA: Is that the trend on the civilian sector?

DR. OSTROFF: Yes.

COL. DINIEGA: And then the -- I think the other thing that doesn't come across too clear is there was some mention of expanding the VAERS expert review committee, to just beyond -- to include vaccines beyond anthrax. Wasn't that one of the comments made?

DR. OSTROFF: I don't remember hearing that specifically, but I think that it's probably not a bad idea, if you have the resources to be able to do that, because, you know, I think as we all know, that there are lots of questions about lots of vaccines.

And so, you know, having a committee available to be able to review those reports that do come in through VAERS is probably helpful in

terms of being able to say yea or no, that this is likely to be vaccine-associated.

DR. LaFORCE: So what we propose, if this makes sense to the other AFEB members, is that Steve and myself would be responsible for drafting for circulation three memos, three responses to the specific questions, one, in terms of the anthrax vaccine and a general statement of concern on the part of the AFEB; secondly, a longer and probably more technically detailed document, about the skintesting or tuberculosis recommendations, answering specifically the questions that were brought out; and thirdly, probably a one-page or not more than that, supporting the surveillance activities, laboratory-based surveillance activities that had been proposed in Col. Kelley's presentation.

COL. DINIEGA: On the military public health, the strong support for laboratory-based surveillance, that should be in addition to the other surveillance -- medical surveillance --

DR. OSTROFF: Yes. It's not in place of.

DR. LaFORCE: Not replace any --

COL. DINIEGA: Not be solely

laboratory --

DR. LaFORCE: No, no. And it actually is complementary to the active surveillance activities that are currently being done in the military.

CDR. TEDESCO: I may have misunderstood, but the statement up there on the anthrax -- More outside oversight is needed --

DR. OSTROFF: This is John's --

CDR. TEDESCO: Yes. I think he said the public perception or the perception out there is that's what's needed and could AFEB, in fact, say something to the tune that there is good oversight already. I just wanted to make certain that's --

DR. LaFORCE: Yes.

CDR. TEDESCO: -- where we were going.

CAPT. TRUMP: I think the words you had used was, the strategy as laid out for ACIP,

National Research Council --

DR. LaFORCE: Very sound, very reasoned, appropriate --

CAPT. TRUMP: It's appropriate.

DR. LaFORCE: -- strategies, with real data and real -- a paper trail that individuals can wrestle with, rather than just simply by innuendo.

COL. DINIEGA: The other strategy besides headed the that, up to NRC for, quote/unquote, oversight and program review was the strategy that they listed on the initiatives, the change in the schedule, the change in the route of administration, the changes in pursuing a new vaccine, which is a different strategy from what Dave just mentioned.

DR. LaFORCE: Right. Excellent point.
Yes.

PROF. BAKER: With your burden of trying to change public perception, have you given thought to possibly actually going to see the editorial departments of New York Times, Washington Post?

I, on two occasions, have gotten editorial staff to turn around their position. One of them was the <u>New York Times</u>, which had opposed air bags, and Bill Hardin [phonetic] and I went up and presented the facts to the <u>New York Times</u>' scientific editorial staff, and they changed their position 180 degrees.

DR. LaFORCE: We offered to -- we sort of offered ourselves --

DR. OSTROFF: Right. What he was

saying is that, you know, there would certainly be opportunities for board members to be able to interact with some of the editorial boards on these newspapers when these issues arise, and he would like to be able to have that opportunity. Mark has certainly offered himself as somebody with longstanding expertise on anthrax.

DR. LaFORCE: And what we would do, as we prepared these background, is perhaps have a briefing document that may have the ACIP draft, for example, which we now have, maybe a couple of the publications that were surfaced, and then just simply distribute it to members of the AFEB, so that if there is something that happens in Madison, for example, we'll say, Well, wait a second; there's an AFEB member who's located in Madison. And if you have a briefing document, you actually -- the material is there.

We'd like to -- what we were proposing is that they ought not to be shy in terms of calling members of the AFEB when individual questions like that arise. In terms of calling a Washington Post, et cetera, I think I'm going to wait.

COL. DINIEGA: We should let the AVIP

office handle that.

DR. LaFORCE: Yes.

COL. DeFRAITES: Just one, I think, point about the newspapers is, I think, we're seeing with the Gulf War illness issue, that, for example, the New York Times for a while made a decision to treat it as a news item, and they kept the science writers off the beat.

Philip Shinon [phonetic], I think, did a series of articles that were -- had a lot of questions about -- in the same token, the Washington Post has David Brown as a physician who writes very good articles. It just depends on where the editor assigns the article. Is it political news? Is it Pentagon news? Or is it a science issue?

I think those who -- at least I've been impressed with Dr. Brown, and he'll call us up and ask for our perspective, and he'll write his own article. But you really feel like you're given a fair deal. It depends on who's writing it.

DR. LaFORCE: Okay. Could I get a --

DR. HAYWOOD: I move acceptance of the three proposals.

DR. LaFORCE: Second?

DR. SOKAS: Second.

DR. LaFORCE: All in favor.

(Show of hands.)

DR. LaFORCE: All right. You taskmaster, we finished.

COL. DINIEGA: Very good, very good.

Administrative business?

DR. LaFORCE: Yes. Administrative business, I've got a couple of things. I met with Ben earlier this year. We were sort of talking about general aspects of the AFEB, and one of the issues we felt --

And I think this meeting exemplifies that if there are specific questions that come, it just is a much more exciting, interesting meeting, because it really forces us to do more work. I mean, it's not like the work is finished. I mean, there's still a ton of work to draft the TB stuff and Stan has some work. I mean, all of us have got more work to do as a result of that.

So one of the feedback or one of the lessons, I think, from this particular meeting is to go back to Col. Diniega and say how successful that was. And if that is sort of a boilerplate in terms of the next set of AFEB meetings, I think

that would be a good strategy.

COL. DINIEGA: The credit for a lot of issues that came up today goes to the Joint Preventive Medicine Policy Working Group, but it's discussed there, and there's agreement on issues that should be brought forward, and they're on the campaign to find more issues.

DR. LaFORCE: Please. This has worked out very, very well.

Stan wanted to make a few comments also, in terms of the AFEB -- or we were talking this morning -- if not, there's no problem.

DR. MUSIC: Remind me.

DR. LaFORCE: No. We were sort of talking about the new membership that's coming, and one of the discussions that I had with Ben was that for new members who are coming to the AFEB, if there was a way that they could be oriented in a more organized way, so that if we have three new members of the AFEB, if they could spend a day meeting or just being oriented, rather than just sort of coming and then sort of learning it by osmosis or whatever, and we think that it would be more focused and you're likely to get more bang if individuals already have a clear idea of not only

expectations, but how certain questions percolate up through the system.

DR. MUSIC: I think an orientation would be very, very useful. I think it would help solidify new members' commitments to attend meetings. We've got several members who unfortunately have not been able to be here. I've been to four meetings, I think, and I haven't seen Ron Waldman once. I haven't seen Dick Jackson once. Who else?

That's not very good, but I think an orientation. I also think we need a little more time. This idea of traveling on the weekend and then having one-and-a-half days -- I think if we brought it up at the front end and got two full days of commitment, we would have a little more time, and we would have at least two nights to be social and hammer out some of the more informal discussions that we don't now have.

DR. SOKAS: I'm going to disagree with that actually, and I don't want to speak for Dick Jackson, but I think that -- I don't think it's a matter of commitment or a lack of it. I think it is time pressure at some point, and that to squeeze in a day and a half is probably the most that a lot

of people are going to be able to --

I mean, maybe there can be variations and there can be optional pieces at the beginning or at the end, or printed materials that people could have access to ahead of time, you know, as kind of orientation materials, or, you know, just other routes of accessing information and condensed down to little sound bites as opposed to reams of paper.

COL. DINIEGA: This meeting was the first meeting there was -- I made a conscious effort to get the read-aheads. Was it helpful?

DR. SOKAS: Yes.

DR. LaFORCE: Oh, very helpful.

DR. SOKAS: Great read-aheads.

DR. LaFORCE: Incredibly helpful.

COL. DINIEGA: So I'll continue to do read-aheads.

DR. SOKAS: And the questions that were going to come from the read-aheads were perfect.

I mean, there was a reason for being here.

COL. DINIEGA: Yes. Most of the time, our questions don't come in until about a few weeks ahead of time, by the time they get -- they have to get signed and --

DR. SOKAS: It's okay. It's airplane reading, Ben. It's okay.

COL. DINIEGA: But I can tell you pretty much in general.

DR. ATKINS: I'd like to second the fact that I think it's difficult to get more than -- I mean, I think conceivably we could do some preparatory work the night before coming in, but to extend it longer, I think is problematic. I run the same problem running the U.S. Preventive Services Task Force.

I do think there ought to be some understanding that active board members attend a certain proportion of meetings. There's no sense carrying members who haven't come, pretending that they're a board member if they haven't been to over 50 percent of the meetings.

COL. DINIEGA: I was telling Dr. LaForce that the expectation that I have, from looking at previous meetings, is that, number one, we can never get 100 percent of the membership here, so I normally count on two-thirds of the membership being here. And that has been running pretty good.

So what I do with the calendars is I'll

go through and see how many people have open days, and for every day of the two-month period that I ask for, four-month period, whatever, over the year, and the days that I can have the highest number of members here are the days that I select.

And then I will also try to get ahead, so that we know today the next two meeting dates, and then the next meeting, we'll know the following, and the next one afterwards, so at least six months to eight months ahead.

DR. LaFORCE: But I'm saying, though, in my capacity as president of the AFEB, I cannot conceive of missing four consecutive meetings. Of what value to -- it's of no value to the Board, missing four consecutive meetings.

I understand how busy everybody -- you know, everybody's very busy, et cetera, but if you're going to be so busy, then the answer should be, I'm sorry; I can't serve; I cannot give you the time.

COL. WITHERS: Is there a rule?

COL. DINIEGA: There's no rule, but the two-year term, when it comes up, then, you know, we have to decide, based on attendance and whatever else --

COL WITHERS: Well, the RAC I'm on throws me off if I miss two consecutive meetings.

COL. DINIEGA: I'm not too sure we'll end up doing that, but --

DR. ATKINS: Well, certainly the farther in advance you have the schedule, the easier that is.

VOICE: If you could schedule a whole year, actually, or tentative dates --

COL. DINIEGA: I would like to. I think I'm getting right to where the months are being -- the right months of the year.

DR. ATKINS: What's the December meeting?

COL. DINIEGA: Oh, December?

DR. ATKINS: September?

COL. DINIEGA: September 12 and 13, and then but there's a meeting before that, May 30 and 31.

DR. ATKINS: Right. I have that one already.

COL. DINIEGA: May 30 and 31 is that Fort Detrick; 12 and 13 of September is going to be in the D.C. area somewhere, but it could be as far out as CHPPM or at WRAIR or someplace like that.

DR. ANDERSON: And I think five of us, the next meeting will be the last meeting.

COL. DINIEGA: Yes. Let me move to the -- the following members are rotating off.

It's impossible to get anybody extended beyond two two-year terms; so four years, then you have to sit out two years before anybody can renominate you.

Dr. Anderson, 18 July; Prof. Baker, 18 July; Dr. Jackson, 17 August; Dr. LaRosa, 18 July; Dr. Reingold, 18 July; Dr. Waldman, 19 May; and Dr. Weinstein was up for renomination, and he declined to be renominated for another two-year term.

So that makes seven members, so we are looking for recommendations for appointments. And what I need minimally is an up-to-date CV and a letter of recommendation from whoever's recommending the person. The process is they come from board members or the surgeon general representatives.

I'll gather them all up, put them on a spreadsheet. It will go to the preventive medicine officers to select on behalf of the surgeon generals in Health Affairs, and then we'll go from there.

Any questions on that?

DR. SOKAS: So any of us can write a letter of recommendation for someone and get their CV.

COL. DINIEGA: And a CV.

DR. ANDERSON: Do you have some that are in process already?

COL. DINIEGA: The last time the selection was made for four new members, there were 13 that were recommended, four selected, and then the agreement among the preventive medicine liaison officers was that unless when I checked with the people who were nominated but not selected, unless they decline -- I will check with the nominees -- they will stay in the running.

DR. ANDERSON: Okay. Yes. That make sense.

COL. DINIEGA: So there will be a pool all the time, and now we're asking for additional personnel.

DR. ANDERSON: How long does it take to get people appointed?

COL. DINIEGA: We started -- the selection was made by the preventive medicine officers back in August, if I'm not mistaken, July, August time frame; the paperwork started moving

forward near the end of September; and Dr. Ostroff was easy because he was a federal employee; that was overnight.

The other three are up at committee management, and my guess is they will be okayed for appointment probably, if not already -- it was getting real close -- in the next couple of weeks to a month. So that's a long process.

DR. ANDERSON: I'm just wondering with --

COL. DINIEGA: Right.

DR. ANDERSON: You just need to be sure that with this number going off after the next meeting --

COL. DINIEGA: Right. We're not down to --

DR. ANDERSON: It would be very helpful if we could get those people, even if they aren't on board, if you've kind of got the finalists, to have them --

COL. DINIEGA: Yes. That's very hard to do.

DR. ANDERSON: -- as consultants.

DR. SOKAS: As consultants, we did it -- the way it used to work was before you were

formally appointed, you would be brought in as a consultant, so that was actually the way that the hit-the-ground-running happened.

COL. DINIEGA: Well, there's a lot of people work with the consultants, too. But the other way I can do it is I will look into -- we were able to get extensions for Dr. Pullen [phonetic] and Dr. Perrotta, so we could hang on to the old board for the next meeting, for September. That would be a two-month extension basically, and then do the transition.

DR. ANDERSON: Our environmental group, half will be going off, so it would be nice to have -- if they could have them on board for the next meeting. Then at least we'd have some overlap.

COL. DINIEGA: Yes. So --

DR. SOKAS: How many in the pipeline are environmental? Just the one?

COL. DINIEGA: Andy and Sue and Dick Jackson.

DR. SOKAS: No. Coming in.

COL. DINIEGA: Oh, coming in.

DR. SOKAS: Of the three who are in --

COL. DINIEGA: Okay. Linda Alexander

is health promotion, and Phil Landrigan is EOH, and then Pierce Gardner is infectious diseases. Oh, Berg, I forgot all about Berg. Berg is infectious diseases, Bill Berg.

And we can have -- I would like to keep the Board at our max. We're 15 -- they say 15 to 20. I'd like to keep it at 20, because of the fact that one-third can't make meetings.

Ergonomics conference, 25 April. So far, Stan, you'll be able to make it. Health Promotion Maintenance, if you'd like to have a subcommittee meeting between now and the end of May, I'll need to know that.

And then the DoD, Weapons of Mass Destruction Conference, is going to be the president, three chairs.

DR. ANDERSON: And then you'll cover the costs?

COL. DINIEGA: Yes. We'll cover the costs. And Health Promotions Committee meeting, we'll cover the costs. Ergonomics conference, we'll cover the cost. You're doing that as official capacities.

And then there's a USUHS clinical conference on injuries, 25 to 26 May also.

PROF. BAKER: I'm going to that.

COL. DINIEGA: You're already going

because you're speaking. Right?

PROF. BAKER: I'm presenting. Yes.

COL. DINIEGA: And then, again, get your travel settlements in. You need to send yours from the IOIPC meeting also, so we can settle that.

And then we'll be in touch via e-mail.

Any questions of me?

DR. LaFORCE: Good job.

COL. DINIEGA: And then the other thing is with Carlson, you know, whenever I get into trouble, I call that 800 number, and they've been very good about helping when you're traveling and you call it. It's manned 24 hours a day. And they'll make the changes.

We are committed, because we are federal employees in this capacity, to using government contracts, so, you know, they'll always give us a hard time when we choose to not go with government contracts.

DR. ATKINS: Even when there's no cost difference?

COL. DINIEGA: Right, because what they want you to do, rather than going in a no-cost

difference, is take the ticket and go make the exchange yourself in a no-cost difference.

DR. ANDERSON: You've got to get a paper ticket, and now they're really pressing.

COL. DINIEGA: Without a paper ticket -- if you get an electronic ticket and try to go to another airline, they're going to send you back to get a hard-copy ticket. So if you think you might be switching tickets, make sure you get -- and I think we've been getting hard-copy tickets.

DR. SOKAS: Not this time.

COL. DINIEGA: Well, I can request that, so you let me know, and I can request it.

DR. ANDERSON: They're pressing very hard to have all the government stuff E-tickets and that really messes up changing airlines.

DR. LaFORCE: Okay. Meeting adjourned.

(Whereupon, at 12:35 p.m., the meeting in the above-entitled matter was concluded.)